Exhibit 1

IN THE UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE: VALSARTAN LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	)
	) No. 2875
	) HON. ROBERT B. KUGLER
This Document Relates to All Actions	)

CONFIDENTIAL INFORMATION
SUBJECT TO PROTECTIVE ORDER
REMOTE
VIDEO-RECORDED
EXPERT WITNESS TESTIMONY OF
ROGER WILLIAMS, M.D.

Thursday, February 17, 2022, 7:18 a.m.

- - - -

REPORTED BY: ELAINA BULDA-JONES, CSR 11720

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Also present:

Kristina Lee, videographer

INDEX OF EXAMINATIONS

INDEX OF EXHIBITS

Page 8

THE VIDEOGRAPHER: Okay. We are now on the record.

My name is Kristina Lee. I am a videographer for Golkow Litigation Services.

Today's date is February 17th, 2022, and the time is 7:18 Pacific.

This remote video deposition is being held in the matter of Valsartan, Losartan and Irbesartan Products Liability Litigation, MDL No. 2875, for the United States District Court, District of New Jersey. The deponent is Roger Williams.

All parties to this deposition are appearing remotely and have agreed to the witness being sworn in remotely. Due to the nature of remote reporting, please pause briefly before speaking to ensure all parties are heard completely.

All counsel will be noted on the stenographic record.

The court reporter is Elaina Bulda-Jones, and she will now swear in the witness.

ROGER WILLIAMS, M.D.,

called as a witness by the Plaintiffs herein, being first duly sworn by the Certified Shorthand Reporter was thereupon examined and testified as is hereinafter set forth.

Page 9

THE REPORTER: Mr. Stanoch.

MR. STANOCH: Thank you.

EXAMINATION

BY MR. STANOCH:

Q. Good morning, Dr. Williams.

A. Good morning, Mr. Stanoch.

Q. Could you tell us where you are located today?

A. I'm in San Francisco, California, in 4 Embarcadero Center in the offices of Greenberg Traurig.

Q. Thank you.

And other than Teva's counsel, Ms. Lockard and Mr. Harkins, and perhaps any tech people, are there anybody else in the room with you?

A. No, there are not.

Q. Other than a box which we have yet to open of potential documents that we sent to your counsel, do you have any documents with you in your room?

A. I see three documents that my counsel has put before me. One is the report, one is the materials considered, and one is the deposition request.

Q. Perfect. Anything else?

A. I have a blank pad of paper and a pen, and

Page 10

nothing else.
Q. Thank you.
Now, you have been deposed a number of times before; is that fair?
A. That's true, Mr. Stanoch.
Q. Right. So you understand the general rules we will be following here today, that I will be asking you a series of questions, you'll be providing answers, everything everyone says on the record will be taken down by the stenographer and on the video; you understand that?
A. I do.
Q. Right. And if you do not understand the question, I ask, please tell me; otherwise I will assume you understand; is that fair?
A. That's fair.
Q. Do you understand you should answer the question unless your counsel instructs you otherwise?
A. I do understand that.
Q. Is there any reason why you cannot testify truthfully and accurately today?
A. There is no reason.
Q. Excellent. Let's do some housekeeping with exhibits, Dr. Williams. First, before we get

Page 11

going, I am going to mark as Williams 1 the revised expert report that your counsel provided to us 20 or so minutes ago.
MR. STANOCH: Stand by, everyone.
(Whereupon, Exhibit 1 was marked for identification.)
BY MR. STANOCH:
Q. So, Dr. Williams, the copy of your report in front of you given to you by your counsel, we will call that Exhibit 1, and for everyone else's benefit, it's available as Exhibit 1 on the electronic shared files. Are you good with that, Doctor?
A. I am.
Q. Excellent. I am going to mark also the revised list of the materials you considered that your counsel also provided a little earlier this morning. Stand by.
(Whereupon, Exhibit 2 was marked for identification.)
BY MR. STANOCH:
Q. Exhibit 2, Dr. Williams, that's the list of materials considered that were provided to us 20 or so minutes ago. You have a physical copy in front of you, I understand, from your counsel,

Page 12

correct?
A. Yes, I do, Mr. Stanoch.
Q. Very good. And as a housekeeping matter, Dr. Williams, could you tell us what revisions were made in the copy of your report that we have marked as Exhibit 1 over the report that was originally provided on January 12th, 2022?
A. Yes. There were two references that needed to be changed.
One was a reference to a guidance of FDA that talks about drug substances for ANDAs. In the unrevised report, that was not provided, so we have now provided that guidance. And it's listed in the materials considered as well as cited in my report. And I'll be glad to answer questions about that guidance if you wish, Mr. Stanoch.
The other change was a reference to a USP guidance that talks about submitting requests for revisions to the United States Pharmacopeia-National Formulary. And the reason for the change was when I looked at it recently, it spoke to requests for revisions of dietary supplements, which of course is not pertinent in this matter. So we changed it to requests for revisions for chemical substances, and that is now referenced in the revised report and

Page 13

also in the materials considered. Again, I'll be glad to answer questions about that document if you wish, Mr. Stanoch.
And then there were two additional documents that were important to my report relating to the Orange Book, and those were not listed in the materials considered, so we adjusted the materials considered to include those references. One was an Orange Book from January 2019 summarizing the prior year, 2018. And then the other Orange Book reference was the Orange Book Supplement No. 8, August for 2018, and those are both referenced in my report and also now listed in the materials considered.
Q. Okay. Thank you, Doctor.
And regarding your report first, I believe the particular footnotes that were updated with the two materials you noted, those are Footnotes 20 and 21 of page 17 of your report; is that right?
A. Let me take a quick look just to confirm. Yes, you have it exactly right, Mr. Stanoch.
Q. Very good. And the materials considered, the two Orange Book references that are now listed in your revised materials considered, I believe it's your testimony that you had relied on them in

Page 14

preparing your report, they just didn't make it into the reliance materials initially; is that fair?
A. Yes, the materials considered listing. But they were referenced in my report appropriately and cited.
Q. Understood. And do you happen to have the page of the reliance materials where the two Orange Book sources are now listed?
A. I'm sure I do, but it might help me if we agree on what page that is.
Q. I think it may be page 2, but if you cannot do it quickly, Doctor, we can certainly take care of it at a break. I don't think there is a controversy on this.
A. Oh, yeah, there it is. It's under "Regulatory Guidances, Standards, and Documents," and there is a 2019 Orange Book, which is the second listing in that category, and then the 2018 Orange Book, Cumulative Supplement 8, August 2018, which is the third listing.
MR. HARKINS: Did we lose Mr. Stanoch?
THE WITNESS: Oh, I think he is looking at the materials considered.
(Whereupon, a brief discussion off the record.)

Page 15

THE VIDEOGRAPHER: Okay. We're going off the record. The time is 7:29.
(Whereupon, a brief recess was taken.)
THE VIDEOGRAPHER: Okay. We're coming back on the record. The time on the video monitor is 7:37. Please begin.
BY MR. STANOCH:
Q. Okay. Doctor, thank you for bearing with us with the technical issues. I believe we were just looking at your revised reliance materials, correct, that's where we were?
A. Yes, I understand.
Q. Uh-huh. And you were showing us, you know, the two Orange Book sources that are now listed under the "Regulatory Guidances" heading, I believe it was, right?
A. Yes.
Q. All right. Other than the updates of Footnotes 20 and 21 of your report, does the revised report that's been produced today have any other changes to it over your original January 12th, 2022, report?
A. No, it does not.
Q. Okay. Thank you.
A. There is a new signature page, Mr. Stanoch, with today's date.

Page 16

Q. Understood. Other than the two footnote revisions we discussed and the new signature page, are there any other changes in your report, now dated February 17th, 2022, over the original iteration of your report from January 12th, 2022?
A. No, there are not.
Q. Okay. And on your lists of materials considered, I think there were a few other things that were added between your original lists from January 12th and today besides the two Orange Book sources. And do you recall that generally, sir?
A. No, actually I can't say I do, Mr. Stanoch.
Q. That's fine. And, you know, for instance, if you look at page 1 of Exhibit 2, your latest iteration of materials considered, there is now a section that says, "Defendants' Expert Reports (with exhibits)." Do you see that?
A. Page 1? Oh, yes, I do see that.
Q. Right. And the first line is the report of Timothy Anderson. Do you see that?
A. I do see that.
Q. And then it continues on, correct?
A. Yes.

Page 17

Q. And you could say it in your own words, but it looks like your revised materials here of 2/17/2022 is showing that you have now reviewed all of the other defense expert reports listed here, whereas you had not reviewed them at the time you rendered your original report of January 12th, 2022; is that right?
A. Yes. I think I did not see these expert reports before I concluded my January 12th report.
Q. Uh-huh. Okay. And so the --
MS. LOCKARD: And just for the record, Dave, the list updating the list of materials with the new expert report was included in the 2/15 production. So just, I think, to clarify, you have received -- prior version that did have the expert reports listed.
MR. STANOCH: No, I agree, Counsel. And this isn't controversial. It's just more housekeeping.
MS. LOCKARD: Right.
BY MR. STANOCH:
Q. But I just wanted to establish, Dr. Williams, that as of the date of your original January 12th, 2022, report, you had not reviewed any defense expert reports in this case, right?

Page 18

A. That's true.
Q. And since then, you did review them all at some point, correct?
A. Well, what I would say --
MS. LOCKARD: Objection. Form.
THE WITNESS: -- is I looked at all of them, and some of them I looked at more carefully than others.
MS. LOCKARD: All of them on the list.
THE WITNESS: All of them on the list, yes.
BY MR. STANOCH:
Q. And because you looked at the defense expert reports on the list we're looking at in Exhibit 2 after you issued your original report, is it fair to say that you did not rely on any defense expert report in rendering your January 12th, 2022, opinions?
A. That's accurate, Mr. Stanoch. Thank you.
Q. Right. And further, because you only noted two changes, to Footnotes 20 and 21, in your report dated today, did anything in the defense expert reports listed here in Exhibit 2 alter or change your opinions as they were originally expressed in your January 12th, 2022, report?

Page 19

A. No, nothing at all.
Q. It also appears, Doctor, looking at Exhibit 2, your reliance materials list of today, page 2, you see "Deposition Transcripts"? Do you see that?
A. Yes, I do.
Q. All right. And I believe you now list four entries there, beginning with, "Transcript of Edward Kaplan," through "Transcript of Ron Najafi Deposition"; do you see those four entries?
A. I do.
Q. Right. And those were not listed in your original reliance materials in January 12th, 2022, right, because these transcripts postdated your report; is that fair?
A. Exactly. You can see that from the date in the first part of each entry.
Q. Absolutely right. And my only point is going to be, Doctor, is that you did not rely on the transcripts of Edward Kaplan, Kali Panagos, John Quick or Ron Najafi in rendering your January 12th, 2022, opinions, correct?
A. That's correct.
Q. And nothing in those four transcripts have led you to change or alter your opinions from your

Page 20

original January 12th report to your February 17th report, right?
A. No, I have not changed my opinions at all.
Q. Very good. Thank you, Doctor. Let's put that aside, and if there is other sort of housekeeping things with the reliance materials, we can hit it later, okay?
A. Thank you.
Q. So, Doctor, your report -- and we will use Exhibit 1, which is the one dated February 17th, 2022, this report includes all opinions you are currently offering in this matter, correct?
A. Yes.
Q. At this time, do you intend to offer any other opinions in this matter besides those reflected in your report, Exhibit 1?
A. No.
MS. LOCKARD: I'm going to object to that, as it calls for attorney work product. Obviously we reserve the right to use Dr. Williams in the liability portion and for liability opinions, but he is not intending to give those opinions today.
Court Reporter, can you hear me?
THE REPORTER: Yes, ma'am.
MR. STANOCH: I heard you too,

Page 21

Ms. Lockard.
MS. LOCKARD: Okay.
MR. STANOCH: I had nothing to respond to.
MS. LOCKARD: Okay. No problem. I just didn't see it come up on the realtime, so I thought maybe we had lost someone, but I see it now.
BY MR. STANOCH:
Q. Doctor, you reference, you know, this litigation by caption in Paragraph 2 of your report, right?
A. I'm looking at Paragraph -- "I make this disclosure," is that what you are talking about, Mr. Stanoch?
Q. Yes, sir. Yes, sir.
A. Yes, that's correct.
Q. And what is your understanding, generally, of this litigation, sir?
A. It relates to the presence of nitrosamine impurities, in terms of my report, in Tab 4, ANDAs that were approved by FDA for Teva. And there are of course many ramifications to that statement, but I'll stop there in terms of what my report focuses on.
Q. And you can look at your reliance materials, Doctor, but I believe you did not review

Page 22

any plaintiff-specific discovery materials, did you?
A. I'm not sure I understand your question. Can you point out what you are talking about on my materials-considered list?
Q. Sure. You did not review any transcripts of any plaintiffs in this litigation, correct?
A. As part of my report?
Q. Correct.
A. Yes, I was speaking particularly in my report about the expert report of Dr. Panagos, Mr. Quick, and Dr. Najafi. But as I already said, I did not rely on the transcript of the deposition to inform my opinions. I was looking more at their expert reports.
Q. Understood, Doctor. You did not review any transcripts of depositions taken of any plaintiff, as opposed to a plaintiff expert, in this litigation, correct?
A. You know, plaintiffs' expert reports, I'm looking at my materials considered, and I think the answer to that question is yes. I did not review plaintiffs' depositions.
Q. Okay. You did not --
A. If I am answering -- yeah. If I am answering your question correctly, Mr. Stanoch.

Page 23

Please help me if you think I didn't.
Q. No, this is not a trick question, Dr. Williams. I agree with you that nowhere in your reliance materials do you list transcripts of depositions taken of a plaintiff, as opposed to a plaintiff expert, so I just wanted to make sure my understanding was correct. And it sounds like we are in accord, right?
A. Yes. Yes. I think we're in agreement now. One of the reasons I was struggling, I was trying to look for something that wasn't on the list, and that's a little difficult.
Q. Of course. And you did not review any documents produced by any plaintiff in this litigation, correct?
MS. LOCKARD: And I'll just make the objection that I'll say it's vague and confusing because I don't know that Dr. Williams knows who produced what. But, I mean, I don't want to answer the question for him, but --
THE WITNESS: Well, yeah, I think Ms. Lockard is stating it correctly. I don't know what was produced by plaintiffs. But I find it hard to believe that they wouldn't have produced some of the material that also came to me from my counsel,

Page 24

but I wouldn't be able to safely say it was -- Mr. Stanoch, does that help?
BY MR. STANOCH:
Q. Well, again, Dr. Williams, this is not trying to be a gotcha. I don't see in your reliance materials, for example, any Bates number for a document that a plaintiff produced the documents. And I just want to confirm, then, you did not look at any documents that were Bates-stamped as being produced from plaintiffs.
A. I think I can agree with that unless my counsel wishes to object.
MS. LOCKARD: No. I assume you are talking about discovery documents. And obviously there are plaintiff pleadings and disclosures and then whatnot on the list, but --
MR. STANOCH: Yes, that's right. And my questions were about discovery materials, Counsel, you know, right. Right.
Q. And, Dr. Williams, again, so you did not review, for example, copies of individual plaintiff pharmacy records that any given plaintiff might have produced, right? You don't recall seeing any of that, right?
A. No, you are correct, Mr. Stanoch.

Page 25

Q. Right. And you don't recall ever reviewing any medical records that a particular plaintiff might have produced in this litigation, correct?
A. I did not.
Q. Uh-huh. And you don't recall reviewing any insurance materials that any particular plaintiff might have produced in this litigation, correct?
A. I did not.
Q. Uh-huh. Do your opinions in this case depend on the number of the potential plaintiffs in the litigation?
A. No.
Q. Right. If this litigation involved one plaintiff or 10,000 plaintiffs, your opinions as expressed in your report would be the same, correct?
A. Yes.
Q. Were you asked to assume by counsel anything for purposes of your report, sir?
A. No, I was not.
Q. Were you asked to assume that Teva's finished-dose valsartan products contained any nitrosamines?
A. Was I asked to make that assumption? No,

Page 26

I was not asked to make that assumption.
Q. Do you have any opinion on whether Teva's finished-dose products did contain nitrosamines?
MS. LOCKARD: Outside the scope of his report. Objection.
THE WITNESS: My understanding is that FDA asked Teva to test some samples of their finished -- of their drug product manufactured under the four ANDAs and that Teva did supply that information to FDA. But it's not something I cited to in my report.
BY MR. STANOCH:
Q. Uh-huh. So you don't know one way or the other whether Teva's finished-dose valsartan products contained nitrosamines?
MS. LOCKARD: Objection. Vague.
I think if you want to ask him if he has personal knowledge, that would be a better question.
THE WITNESS: Well, in any case, I do recall seeing some numbers that Teva provided to FDA, but they are not in my report and I don't recollect them now.
BY MR. STANOCH:
Q. Uh-huh. And you are not opining, are you, Doctor, on the levels of nitrosamines that may or

Page 27

may not have been in Teva's finished-dose products, correct?
A. No, I'm not.
Q. Uh-huh. Were you asked to assume by counsel that Teva's finished-dose products did not contain nitrosamines?
A. No, I was not.
Q. Uh-huh. Were you asked to assume that Teva had no knowledge about the chemical synthesis processes necessary to create valsartan API?
A. I was not asked to make that assumption.
Q. Okay. Right. You were not asked to make any assumptions in rendering your opinions, correct?
A. Yes, that's correct.
Q. Okay. When an API manufacturer becomes aware of a potential genotoxic impurity, sir, what should they do?
MS. LOCKARD: Objection. Form. Outside the scope -- his report and the class-certification phase.
THE WITNESS: The way I would answer that, Mr. Stanoch, is it depends on when the discovery was made. If it is during the development process, prior to approval of either the NDA or ANDA, a company may be able to mitigate the presence of the

Page 28

impurity. After approval, it depends on a number of factors, including -- I'm sorry, Mr. Stanoch. Were you asking generally about impurities, genotoxic impurities, or nitrosamine impurities?
BY MR. STANOCH:
Q. Potential genotoxic impurities generally, not specific to nitrosamines at this question.
A. Okay. Good. I would say after approval, if such an impurity is discovered, I think there would be an attempt to work with FDA for a marketed drug in the United States to determine what the limit should be and what corrective action should need to be taken.
Q. Uh-huh. Should a API manufacturer who becomes aware of a potential genotoxic impurity in API notify their customers who buy that API?
MS. LOCKARD: Objection. Outside the scope of Dr. Williams' class-certification report opinions and gets into the liability issue.
THE WITNESS: Well, I'm thinking of the specific example in this matter where, yes, you know, the API manufacturer did inform customers. So I would say that is a good practice in my personal opinion.

Page 29

BY MR. STANOCH:
Q. You mentioned in your answer the API manufacturer did inform customers here. What do you mean?
A. Well, if I understand the history in this matter, Prinston, which is a company associated with ZHP in China, did inform FDA that they were finding the NDMA nitrosamine impurity, and I think in turn then FDA began working with the various manufacturers using the ZHP drug substance.
Q. Uh-huh. When, to your recollection, did ZHP become aware of the potential nitrosamine impurities in valsartan API that you alluded to in your prior answer?
MS. LOCKARD: Objection. Speculation.
THE WITNESS: I think we can look at my report.
BY MR. STANOCH:
Q. Sure.
A. Is it all right if I look at my report now, Mr. Stanoch?
Q. Of course, Doctor.
A. I would say when this became generally known to the public was July 13th, 2018, with the first FDA press release. And FDA noted in the press

Page 30

release that their understanding came from Prinston Pharmaceuticals, as I said, which in turn, became aware of the impurity through the efforts of ZHP. And when we are talking about the impurity, we are talking about NDMA.

Q. Okay. What paragraph are you looking at, Doctor, so we can be on the same page?

A. It's Paragraph 92.

Q. Right. And this is the July 13, 2018, reference to an FDA press release about NDMA in the ZHP valsartan API. My question was: When do you recall that ZHP became aware of the NDMA impurity in the valsartan API?

MS. LOCKARD: Objection. Form. Speculation.

THE WITNESS: Yes, I don't think I have that information in my report or that I cited to it.

BY MR. STANOCH:

Q. You don't know when ZHP discovered the potential NDMA impurity in valsartan API?

MS. LOCKARD: Same objection. Asked and answered as well.

THE WITNESS: I don't think I stated it in my report, Mr. Stanoch.

Page 31

BY MR. STANOCH:

Q. Don't you think it would be important for you to know when ZHP became aware of the potential for NDMA impurities in valsartan API in rendering your opinions?

MS. LOCKARD: Objection. Argumentative.

THE WITNESS: Remember, I'm speaking to Teva, so, you know, for the most part, I don't focus on ZHP. I'm talking about Teva's actions in the context of the finding of nitrosamine impurities.

BY MR. STANOCH:

Q. Wouldn't you need to know, sir, when ZHP became aware of the NDMA in valsartan API to assess when Teva, as the customer, should have known about that as well?

A. No, I don't believe so. I think Teva was aware in the weeks before the FDA press release. But again, my focus is on Teva's activities and what they did when they became aware of the presence of nitrosamine impurities in the ZHP drug substance.

Q. Let's focus on Teva. When did Teva learn of the potential for NDMA genotoxic impurities in valsartan API?

A. Well --

MS. LOCKARD: I'm going to object to that

Page 32

as vague to the extent you are asking about potential genotoxic impurities.

MR. STANOCH: How would you like me to fix the question, Counsel?

MS. LOCKARD: Well, if you are asking about nitrosamines, the presence of nitrosamines, that's more specific than potential genotoxic impurities.

MR. STANOCH: Okay. I withdraw my prior question.

Q. Doctor, when did Teva become aware of the potential nitrosamine contamination in valsartan API?

A. It was around the time Teva put on hold the manufacture of its four ANDAs because of the presence of these impurities in the ZHP drug substance.

Q. Uh-huh. And when --

A. And that, I believe, was in June of 2018. Then there were a number of activities that Teva undertook, which of course is a core part of my report, but the most important one in terms of my report were the recalls of the products that contained the ZHP drug substance.

Q. Okay. Should a drug manufacturer such as

Page 33

Teva have quality systems in place to ensure that its API suppliers notify them upon the discovery of potential genotoxic impurities?

MS. LOCKARD: Objection. Outside the scope of the class-certification expert report.

THE WITNESS: Yes, I did not comment on that in my report. If you are asking me as a personal question, I could say I would think it likely that Teva would have that kind of agreement or understanding.

BY MR. STANOCH:

Q. Uh-huh. Did you undertake to assess whether that agreement or understanding existed here between Teva and ZHP for valsartan API?

A. No, that was not part of my report or my opinions.

MS. LOCKARD: Objection. That's outside the scope of the expert report on class-certification issues.

BY MR. STANOCH:

Q. Isn't it a finished-dose manufacturer's responsibility to obtain material information about genotoxic impurities from their API source in a timely manner?

MS. LOCKARD: Objection. It's liability

question. It's outside the scope of the class-classification expert report opinions.

MR. STANOCH: Counsel, you have said outside the scope and liability issue a number of times. Could you just -- I'm not picking a fight. I just want to know what you mean by that.

MS. LOCKARD: Well, okay. We are in the class-certification phase of the case, correct? There are opinions that are very specific that have been directed by Dr. Williams in his report. These are not liability opinions.

The majority of your questions so far this morning have been, what should manufacturers do? What should their quality systems be? And they are all liability opinions, and that is not the substance of his report. That's not within his report. These are squarely liability questions.

MR. STANOCH: Well, I appreciate that, Ms. Lockard. I'll just say I don't necessarily agree with you that these are outside the scope of the report that he has issued at class, but I'll note your objection and we can keep going.

I'm sorry, Madam Reporter. Would you be kind enough? Did I have a question pending?

THE REPORTER: Let me check for you.

MR. STANOCH: Thank you.

(Whereupon, the reporter read the record as follows:

"Question: Isn't it a finished-dose manufacturer's responsibility to obtain material information about genotoxic impurities from their API source in a timely manner?")

MS. LOCKARD: Same objection.

THE WITNESS: You know, the understanding that a drug substance and the corresponding drug product may have genotoxic impurities has been a challenge to FDA and the pharmaceutical industry over many years. The FDA guidance that spoke to how to deal with that actually came out in 2015.

So when you ask a general question like that, it's very difficult for me to answer. But definitely if the manufacturer of a drug product feels there could be a genotoxic impurity, there is an obligation to work with FDA to understand that and to limit it if necessary.

I hope that's responsive to your question, Mr. Stanoch.

BY MR. STANOCH:

Q. Partially, but I appreciate you trying, Dr. Williams. I really do.

The next question: What common evidence would you need to look at to determine whether it is a finished-dose manufacturer's responsibility to obtain important information about genotoxic impurities from their API source in a timely fashion?

MS. LOCKARD: Objection. Vague. Confusing. Outside the scope of the class-certification expert report.

Did you say common evidence? Or I might have misheard you.

THE WITNESS: Are you waiting for Mr. Stanoch to answer, Ms. Lockard?

MS. LOCKARD: It's okay. I was, but I have the -- I see on the transcript what he said.

All right. I stand by the objection.

THE WITNESS: You know, the way I would answer it, Mr. Stanoch, it's a very general question. It's probably more important to focus on nitrosamine impurities because that's what my report focuses on.

And all I can say is FDA at many points in this episode said that the finding of these genotoxic nitrosamine impurities was unexpected. So I don't think I can speculate as to when either a

drug-substance manufacturer or a dosage-form manufacturer would expect something that was -- or anticipate something that was unexpected. I think it's important to keep in mind that these impurities were unexpected.

BY MR. STANOCH:

Q. Are you finished, Doctor?

A. Yes.

Q. Thank you.

I may ask you that from time to time, just for the video, to make sure I don't step over you and vice versa; is that okay?

A. Yes, no problem, Mr. Stanoch.

Q. Thank you. I appreciate your patience there.

You said "unexpected" a number of times in your answer there, and we will certainly get to that. But let me -- you said that my question would be different if I asked about nitrosamines versus genotoxic impurities generally, so I'm going to ask you the question differently.

Question: What evidence would you need to look at in order to determine whether it is a finished-dose manufacturer's responsibility to obtain important information about nitrosamine

Page 38

impurities from their API source in a timely fashion?
MS. LOCKARD: Objection. Vague. Confusing. Outside the scope of the class-certification expert report.
THE WITNESS: You know, it might be helpful, Mr. Stanoch, to back up a little bit on what are the responsibilities of an ANDA filer in terms of assessing impurities in its drug substance and its drug product.
The presence of genotoxic impurities I would say doesn't really come up too often in that primary responsibility. So I think you are asking for something that, if I may say so, is not routine as part of the ANDA requirements or recommendations by FDA.
BY MR. STANOCH:
Q. Are you saying it's not the responsibility of a drug-product manufacturer to identify potential genotoxic impurities?
MS. LOCKARD: Objection. Clearly outside the scope of the class-certification opinions in the expert report. It's clearly a liability question.
MR. STANOCH: This is his last answer, Counsel.

Page 39

Q. Go ahead, Mr. Williams.
A. What I would say, Mr. Stanoch, is, you know, the ANDA applicant has a responsibility to look at the impurities in their drug substance and their drug product and decide whether they need to be reported, identified, and qualified. And those are general recommendations that appear in the guidances I cited.
It was only until 2015 that FDA produced the guidance on how to deal with genotoxic impurities, and that, of course, came to a head three years later with the finding of the nitrosamine impurities.
So I really can't answer your question about the responsibility of a drug-product manufacturer other than to refer you to that 2015 guidance.
Q. You are saying there was no guidance to the drug industry about genotoxic impurities until 2015?
A. No, I think there were guidances, which I allude to in my report. But the M7 guidance that we're talking about now I think clarified it in terms of how manufacturers need to focus on the possibility of genotoxic impurities.

Page 40

Q. Was there any industry guidance on genotoxic impurities prior to 2015, Doctor?
A. I think if we look at my report, I could find reference to other documents that had been produced by FDA or the EMA or in ICH, so -- and those documents preceded the 2015 guidance.
Q. Do you agree that a drug-product manufacturer is ultimately responsible for the API that it incorporates into its finished-dose product?
A. Yes, I think that's generally a fair statement, Mr. Stanoch.
Q. Yeah. So Teva is ultimately responsible for the valsartan API that was in its finished-dose valsartan product, correct?
A. Yes, I think I can agree with that.
MS. LOCKARD: Objection. It's vague.
BY MR. STANOCH:
Q. And that would include the identification, characterization, testing, and control of any potential genotoxic impurities, correct?
MS. LOCKARD: Objection. Compound. Vague. Outside the scope of the class-certification expert report.
THE WITNESS: Well, remember, ZHP and Teva are working according to FDA requirements that speak

Page 41

to identity, strength, quality, purity, and potency. When we talk about purity, we're talking about impurities.
And the guidances that ZHP and Teva would use are the ones I cited in my report, both the ICH Q3A and Q3B with revisions, and then also the corresponding ANDA guidances. None of those guidances mention genotoxic impurities.
BY MR. STANOCH:
Q. Are you saying, then, that Teva had no obligation to potentially identify genotoxic impurities in its finished-dose valsartan products?
MS. LOCKARD: Objection. Vague. Outside the scope of class-certification expert report.
THE WITNESS: You know, I think it's clear in my report that FDA gives recommendations in these guidances, and that is what Teva and ZHP would be following to submit their ANDA to FDA for review and approval.
Now, if FDA had some concern about genotoxic impurities based on the route of synthesis of the drug substance, they could certainly bring that to Teva's attention or the DMF-holder's attention, in this case, ZHP.
But again, to talk about it generally in

Page 42

terms of responsibility and liability is not something I dealt with in my report.
BY MR. STANOCH:
Q. Uh-huh. So you are not offering any opinion at this time about which firm would be responsible for the identification of genotoxic impurities in Teva's finished-dose valsartan product?
A. I think if there was some reason to suspect the presence of a genotoxic impurity, any drug manufacturer would have to consider that and discuss it with FDA in terms of what to do, but that was not the case here.
Q. Uh-huh. Would it be your expectation that Teva would have had systems in place to assure that ZHP would promptly notify it in the event ZHP identified a potential genotoxic impurity in valsartan API?
MS. LOCKARD: Objection. Vague. Outside the scope of the class-certification expert report.
THE WITNESS: You know, again, you are asking these very general questions, but I would say both ZHP and Teva are sort of marching, if you will, to laws, regulations and guidances that come from FDA, and for the most part those guidances don't

Page 43

speak to genotoxic impurities.
So if you are talking about a general moral obligation, I could only answer in a personal opinion, but I'm really trying to focus on the regulatory requirements for an ANDA to be considered and, if possible, approved.
BY MR. STANOCH:
Q. Well, Doctor, you are opining on whether or not Teva followed GMP or proper regulatory practice, I'm looking at Paragraph 116, right?
A. 116 speaks to Dr. Najafi's report. Is that where we're looking, Mr. Stanoch?
Q. Oh. Well, that might be a separate issue, Doctor. You know, your January 12th report, the numbering -- there is two Paragraph 116s. It went from 116 to 127, and then it restarted at 110. I was looking at your conclusion. Maybe you fixed that in your latest report. Let's take a look.
A. I'm sorry for those typo errors.
Can you point me exactly to where you are looking, then? Is there a page number?
Q. I am looking at page 46, Doctor.
A. Okay. Good.
Q. And you see the heading "Conclusion"?
A. Yes, I do.

Page 44

Q. Right. And the paragraph number there is 116. Do you see that?
A. I do. I do see that. Thank you.
Q. Right. Sure.
A. And your question about that is? I'm sorry.
Q. Yeah, we will get back to that. Let's do this housekeeping. So we scroll back up, that's actually some misnumbering issue. You have another Paragraph 116 starting under "Dr. Najafi's Declaration" on page 38, right?
A. Yes, I apologize for these errors. I'm sorry.
But I'm sure we can find the part of the report that you want me to talk about.
Q. Sure.
A. So --
Q. Well, hold on. Hold on. Sure. We could fix. And just to button this up, so then it looks like your paragraph numbering restarts, for the record, on page 44, under the "Rebuttal to Mr. Quick's Expert Declaration." Do you see that?
A. Yes, I do. It jumps from 127 and then to 110.
Q. Right.

Page 45

A. So I think to make sure we're always talking about the right thing, I think if we just give the paragraph number and the page, we should be fine. Would that be all right with you, Mr. Stanoch?
Q. Absolutely fine. And, Doctor, was there some cutting-and-pasting issue with the section on your rebuttal to Mr. Quick that messed up your numbering of your paragraphs here?
A. No, I would say it was a word-processing error, where you have to sort of back up and make sure that the Word program numbers the paragraph correctly.
Q. Sure. I have been there, Doctor. I'm sure we all have.
No, did you write this whole section, the "Rebuttal to Mr. Quick's Expert Declaration" in your report?
A. I would say, you know, I wrote the report, and I apologize for the limits on my word-processing skills.
I did try to correct this. I think we noticed some of the misnumbering when we were looking at drafts, and apparently I failed to do it in the final document.

Page 46

Q. Again, that's totally understandable. I was just getting at -- to say if you wrote this section here, "Rebuttal to Mr. Quick's Expert Declaration," or not?
A. Yes, I did.
Q. Uh-huh. And no one gave you that to cut and paste into the report and that messed up your numbering?
A. No.
Q. Uh-huh. You said "we" noticed some pagination errors before. Who is the "we" in your answer a couple answers ago?
A. Well, first of all, it's not a pagination error, it's a paragraph-numbering error. I can tell you exactly how it happens. But I think when we were looking at drafts, one of the counsel pointed out that the numbering was not consistent.
Q. Okay. Moving on, I'm looking at page 46, your "Conclusions," Doctor. Tell me when you are there.
A. Okay, Mr. Stanoch, I'm there.
Q. And the Paragraph 116 on this page, you write in part, "Teva did not fail to follow cGMP or proper regulatory practice." Do you see that?
A. I do.

Page 47

Q. Right. So you are opining on whether or not Teva followed cGMP and proper regulatory practice, right?
A. Yes.
Q. Right. So in the context of your opinions on cGMP and proper regulatory practice, my question, now several questions ago is: Do you believe that Teva was following proper regulatory practice in terms of its relationship with ZHP to ensure that it was promptly notified about potential genotoxic impurities in valsartan API?
A. I think the answer is yes. I think ZHP was communicating to Prinston, they were communicating with FDA, FDA was communicating with Teva. And Teva promptly recalled all these products, as my report says. So to me, that's the way the system should work.
And Teva never was under any particular GMP failure notice from FDA. I think FDA was pleased with the way Teva worked out its recalls in order to protect the public when they found out about the nitrosamine impurities. I don't see a failure, Mr. Stanoch. I see success.
Q. So you are saying, Doctor, that Teva acted reasonably promptly in the summer of 2018 upon

Page 48

learning from ZHP about the NDMA in valsartan API?
A. You know, you are asking a question that sort of asks me to take your word for it. I don't think I commented on when ZHP or FDA actually informed Teva, but it was certainly in the May, June, July time frame, and I think Teva acted promptly to recall two of its ANDA valsartan products from the U.S. market.
And that's the way the system is supposed to work. That's what recalls do. It allows the removal of a product that, for one reason or another, needs to be removed from the market, either because it fails GMPs or it fails a specification.
What is unusual, and I noted this in my report, is the recall occurred before FDA had set a limit on the nitrosamine impurity. So Teva was acting, and I'm going to use FDA words, with what I might call an abundance of caution to remove the two valsartan products manufactured in Malta from the U.S. market.
Q. Uh-huh. So what I hear you saying is the system worked as it should here.
ZHP discovered NDMA in valsartan API sometime in the summer of 2018 or shortly before, right?

Page 49

A. Yes, I think you are saying it correctly, Mr. Stanoch.
Q. ZHP told Teva, correct?
A. Well, again, I'm not sure of the routes of communication. I think Prinston told FDA and FDA told Teva, and pretty soon everybody is talking about this difficult situation.
Q. Well, that's fine, whatever your understanding of the route is. So ZHP told its affiliate company, Prinston, right?
A. If you want to postulate the route of communication, that's fine with me, Mr. Stanoch.
Q. No, I'm not postulating anything, Doctor. I'm just trying to -- whatever your understanding is, I'm not bickering with it. I'm just trying to make sure I establish what you think the route is, right? So ZHP, we already determined, identified NDMA in valsartan API in 2018, right? We agree with that?
A. And that information came to Prinston and Prinston brought it to FDA, and then FDA started looking at all the manufacturers of valsartan, and there were several, who used the ZHP product. And that included Teva for two of its four ANDAs.
Q. So how did the information about the NDMA

Page 50

in 2018 get to Teva?
A. I would be speculating, but to me, it might have come from FDA.
Q. Well, whatever you think your answer is. I'm just trying to see what the telephone route of communication is.
And that's what you were referring to more generally as the system working, that the API manufacturer passed the information along, and it went to the FDA and at some point it got to Teva, and then Teva, as you said, instituted its recalls for its product that contained the valsartan API, right?
MS. LOCKARD: Objection. Vague. Compound. And outside of the scope to the extent this line of questioning is asking about what ZHP did or should have done.
THE WITNESS: Yeah, I don't want to get into the details of the way you described the routes of communication, but I can certainly say that when these things come up, everybody needs to talk to everybody, including FDA, and FDA is the one that prompted Teva to make the recalls.
BY MR. STANOCH:
Q. Yeah, right. You opine that FDA asked

Page 51

Teva to recall its valsartan containing the API from ZHP, right?
A. Well, the recall was voluntary on Teva's part, but they certainly worked closely with FDA to make sure that FDA was satisfied with the way their recall occurred.
Q. Uh-huh.
A. And that recall was in, I want to say, June of 2018. Wait a minute. I may have the month wrong. I'm sorry, Mr. Stanoch. I can check that if you wish.
Q. Well, I'm looking at Paragraph 109 of your report, Doctor. Tell me when you are there.
A. All right. Which paragraph?
Q. 109.
A. And I see that on -- can you say the page, Mr. Stanoch?
Q. 37, sir.
MS. LOCKARD: It starts on 36.
THE WITNESS: Okay, yes. I see that, Paragraph 109 on page 36.
BY MR. STANOCH:
Q. Stand by. Right. Yeah, you know, I have the earlier version of your report, not the one given to me this morning, so I'm sorry if I'm off by

Page 52

a page number. But yes, your Exhibit 1, page 36, Paragraph 109. It begins, "Somewhat unusual," right?
A. Yes. Yes. We are in the same place, Mr. Stanoch.
Q. Perfect. And you wrote, "the FDA asked for recalls of drug products"; do you see that?
A. Yes. I do see that. And I think that corresponds with what I said previously.
Q. Right, right, right. Well, you were saying that FDA and Teva were talking previously, but you write in your report that FDA asked for the recalls, right?
A. Well, FDA works with the manufacturer to make a voluntary recall. I would say the decision on the recall is up to the manufacturer.
Q. Well, that's not what you wrote here in Paragraph 109, is it?
A. You know, I think the way it works is FDA wishes a recall, and a manufacturer -- I don't think FDA has the authority to compel a recall. So the reason I say it's voluntary is it's up to Teva to say, yes, we will do this recall at your request, and that's what Teva did.
I don't think we should quibble about, you

Page 53

know, who was actually driving the decision. I think it's a joint decision between FDA and Teva, but it's a voluntary act on the part of Teva.
Q. Well, you know, Doctor, I can only ask questions about what you opine and write in your report, and what you wrote in your report twice in this paragraph is about the FDA asking for these recalls, correct?
A. That could well be how a recall occurs, FDA finds something and they work with the company to execute a recall. But Teva was voluntarily making these recalls, and they did so successfully. And they kept FDA apprised of what they were doing, and FDA agreed with it.
Q. Well, you don't write here in this paragraph or anywhere in your report that Teva went to the FDA and said, we're going to recall our product, did you?
A. You know, I stand by the words in the document. Are you providing alternate words, Mr. Stanoch?
Q. I'm not providing anything alternate, Dr. Williams. I'm focused on your words in Paragraph 109 of your report, where you twice say the FDA asked for the recalls.

Page 54

A. Yes, I have no problem with FDA asking for recalls. Does that seem a problem in terms of how Teva executed the recall?
Q. I'm trying to establish based on your words in your report, Doctor, that Teva did not go to the FDA and said, we need to recall our product, rather, the FDA asked Teva to recall the valsartan product, correct?
A. I'm not going to debate the words with you. I think you are right, Mr. Stanoch, that Teva -- FDA was asking Teva and Teva responded to this request. It was voluntary because I think Teva could have said, no, we're not going to recall. Teva did not do that. They voluntarily recalled.
But you are right, Teva initiated the request based on their findings working with ZHP and other manufacturers.
Q. I'm going to go back to sort of the chain of communication about the NDMA discovery in June 2018. So do you think there was any direct communication between ZHP and Teva about the NDMA discovered in June 2018?
A. Well, I would have to speculate. It may be in my materials considered, but I didn't cite anything in that report, so at this point it would

Page 55

be speculative for me to answer. I would be very surprised if ZHP and Teva weren't communicating on this point.
Q. Okay. Would it be proper regulatory practice for ZHP to be in communication with its customer Teva about the discovery of NDMA in the valsartan API?
MS. LOCKARD: Object to the extent you are asking him about what ZHP should or shouldn't have done. It's outside the report.
THE WITNESS: It seems to me, if a drug-substance manufacturer finds an unidentified impurity that is problematic in their drug substance, they would certainly notify their purchasers.
BY MR. STANOCH:
Q. What cGMP procedures did Teva have in place to assure that ZHP would inform Teva about any genotoxic impurities in APIs that Teva was purchasing?
MS. LOCKARD: Objection. Vague. Scope.
THE WITNESS: You know, Mr. Stanoch, we may look for it in my materials considered, but I did not study that to form my opinions, and I don't think I cite anything into that part of my -- any

Page 56

part of my report. And I'm not a GMP expert, so I very carefully combined my GMP opinions through brief statements in this report.
BY MR. STANOCH:
Q. That's confusing to me, Doctor, because the conclusion paragraph we were looking at is you are opining that Teva did not fail to follow cGMP or proper regulatory practice, right?
A. And I base that on my review of inspections of Teva that occurred over the decade of 2010 to the present time. Teva did not have GMP issues insofar as FDA was concerned, including GMP issues related to the nitrosamine impurities.
Q. So the only basis for your opinion that Teva did not fail to follow cGMP or proper regulatory practice is the status of any FDA inspections of Teva finished-dose facilities?
A. Yes, exactly. And that's where I spent some time in my report, on that inspectional history, and for the most part, I did not see any particular GMP problems that FDA was bringing to Teva's attention.
Q. So your opinions are not based in any way on Teva's compliance with cGMP or proper regulatory practice vis-à-vis its API suppliers ZHP and Mylan?

Page 57

MS. LOCKARD: Objection. Vague. Confusing.
THE WITNESS: Yes, I did not explore separate from FDA inspections how Teva's SOPs conform to FDA's requirements on GMPs. That was not part of my report.
BY MR. STANOCH:
Q. Okay. Well, why do you list all Teva's SOPs in your reliance materials, then, Doctor?
A. There is a huge amount of material in my materials-considered document, and I would say only a small fraction of that was cited in my report, and even that small fraction was voluminous.
Q. So am I to take it, then, that the materials that you only relied on for your opinions at this stage are the ones quoted in the -- or cited in the body of your report, not all of them listed in your reliance materials?
A. No, I think if it is cited in my report, it should be listed in my materials-considered list. Was that your question, Mr. Stanoch?
Q. No. My question is a little different, Doctor. You know, you list a lot of stuff in your reliance materials, including Teva's SOPs, but now you are telling me your opinions don't turn on

Page 58

Teva's SOPs as it relates to Teva's relationship with its API suppliers, right?
MS. LOCKARD: Objection. Lacks foundation. Vague. Misstates the document.
THE WITNESS: Yes, I think I make -- my opinions are clearly stated both at the beginning and at the end of the report and I provide citations to support those opinions, but I certainly didn't get into the adequacy of Teva's SOPs with regard to conformance to FDA's GMPs. That would have been a completely different report.
BY MR. STANOCH:
Q. So how am I to know from your reliance materials, Doctor, which materials you are relying on, the opinions in the body of your report?
A. I think the best way I could answer that, Mr. Stanoch, is to look at the citations in my report, which are also listed in the materials considered.
Q. Got it. So --
MS. LOCKARD: Objection to that question because you continue to name the list of materials considered as his reliance materials, which is confusing and vague and lacks foundation.

Page 59

BY MR. STANOCH:
Q. So let me make sure I fully understand it, then. So the materials you rely upon to render your opinions reflected in your report are the ones that are cited in the body of the report?
A. Yes, I think as a general statement, Mr. Stanoch, that's correct. And as you can see, it's only a small fraction of all the materials listed in the materials-considered document.
Q. Okay. So if an item is listed in your materials considered but not cited in the body of the report, you are not relying on that material in rendering your opinions at this time?
A. I think I can agree with that.
Q. That's fine. It will make the day go faster, Doctor. Again, I just want to make sure we're on the same field. I appreciate that.
MS. LOCKARD: So I think we have been going about an hour, if you are at a point in time -- you are changing topics --
MR. STANOCH: That's fine. Doctor, would you like a break?
THE WITNESS: That would be very nice, Mr. Stanoch.
MR. STANOCH: Let's do it.

Page 60

THE VIDEOGRAPHER: Okay. So we're going off the record. The time is 8:42.
(Whereupon, a brief recess was taken.)
THE VIDEOGRAPHER: Okay. We're coming back on the record. The time on the video monitor is 8:51. Please begin.
BY MR. STANOCH:
Q. Doctor, just yes/no, did you talk to your counsel during the break?
A. Yes, I did.
Q. Did you talk to anyone else?
A. No, not at all.
Q. Did you look at any documents?
A. Did we look at any documents?
Q. Correct.
A. I think there was one document we looked at.
Q. What did you look at?
A. It was a management document of Teva that went out globally to many scores of people about -- and it's cited in my report -- about the problem with the ZHP drug substance having nitrosamine impurities.
Q. Where is that cited in your report?
THE WITNESS: Can you tell me where it is

Page 61

in the cited materials?
Okay. It's on page 9, and it's Reference 9 on page 9, I believe.
BY MR. STANOCH:
Q. Is that "Notification Letter from Valsartan re" -- sorry. Start over. "Notification Letter from re Valsartan" "update"?
MS. LOCKARD: Just to clear it up, it's -- sorry, you're not trying to -- I know you are just trying to figure out which document it is. The document is 565758.
THE WITNESS: Yes, and it's Reference 9. There are actually two references in Reference 9, and it's the first that we looked at briefly.
BY MR. STANOCH:
Q. Why don't you tell me the Bates numbers of the two documents you looked at?
MS. LOCKARD: He looked at one document. He is saying there are two documents referenced in Footnote 9.
MR. STANOCH: Oh, I'm sorry, Counsel. I thought he was looking at his materials considered. We are looking at his footnote in his report. Thank you. That's helpful. I see it now, thank you.
Q. Did that document refresh your

Page 62

recollection about anything you had looked at before?
A. No. I don't think it's really pertinent to the questioning. I'm glad to ask questions about it if you wish, Mr. Stanoch.
Q. Sure. I just need to get a copy of it and to share it for all of our colleagues who are remote, so give me one second. Okay. We will mark that document as Williams Exhibit 3.
(Whereupon, Exhibit 3 was marked for identification.)
THE WITNESS: And if I -- Mr. Stanoch, may I point out something in the document that was helpful to some of your questions?
BY MR. STANOCH:
Q. Before you do that, let's make sure I have the same document as you. I'm going to share my screen, Doctor. You will see it looks like a -- it's an e-mail from June 21, 2018, Bates No. 565758. Is this the same document you are holding?
A. Yes, I believe so.
Q. Great. I'm going to stop sharing now that we're on the same page.
This is the document you were referring to that you looked at, right?

Page 63

A. Yes. And if you look at the four-digit page number ending 5763 --
Q. Okay.
A. -- you can see at the top there is a reference to when ZHP informed Teva that "they came to be aware of a previously unknown impurity that may have genotoxic potential," and that was on June 20th, 2018.
Q. Got it. And it's your opinion that Teva acted appropriately, promptly, after receiving notification from ZHP on June 20th, 2018?
A. Yes. The way I would say it, if you look further down, where it says "Investigation," "sites to requested to remove any materials or products using Valsartan API from Zhejiang" -- ZHP.
So to me, you know, this is a very rapid response on the part of Teva to a problem brought to their attention by ZHP. Remember, the date of the e-mail is 6/21 and they are notified by ZHP on 6/20, so I don't think you could have a much more rapid response.
And then subsequently to this notice, Teva also issued the recall. And I believe that was in July 16th, 2018, so that was about a month later.
And again, as we discussed before the

Page 64

break, FDA asked for the recall, but Teva voluntarily did the recall, working with FDA and to FDA's satisfaction.
Q. You think it was appropriate for Teva to wait, as you said, a month later after being told by ZHP about the NDMA impurity, to institute its recalls?
MS. LOCKARD: Objection to the form of that question. It lacks foundation and it misstates the evidence.
THE WITNESS: Well, you know, you can imagine, I'm speaking generally, not to anything I said in my report, but this is an incredibly difficult finding, inspecting a company making products all over the globe, including FDA. And of course FDA is a very stringent regulatory authority, so it doesn't surprise me at all that by the time they sorted through the issues, it took about a month to get the product off the U.S. market.
BY MR. STANOCH:
Q. Okay.
A. And that's what my report says. And at no time was Teva's product ever deemed adulterated or misbranded, and it was always AB-rated. So I think Teva acted with incredible swiftness.

Page 65

And remember, the issue is not could the nitrosamine impurity be there or not. It could be there. It just didn't have a limit. And FDA set that limit in December 2018.
Q. Uh-huh. Well, nothing stopped Teva from taking its valsartan with ZHP API in it off the market sooner than when the FDA asked, right?
MS. LOCKARD: Objection. Vague.
THE WITNESS: No, I think you're asking for sort of a personal opinion. It seemed to me it happened remarkably quickly, Mr. Stanoch. It wasn't anything that was delayed.
You know, to issue a recall and discuss with the FDA how to do the recall takes some time. So if you ask me, a few weeks, was that unusual, I don't think it was unusual at all.
BY MR. STANOCH:
Q. Uh-huh. It's your opinion that this is how it's supposed to happen, right? ZHP became aware of the impurity, looks like they told Teva, and then Teva acted, based on this Exhibit 3, right?
MS. LOCKARD: Objection. Vague.
THE WITNESS: Again, it -- I think I'm speaking personally, but I think Teva's activities here were highly responsible and laudatory.

Page 66

BY MR. STANOCH:
Q. Okay. And would you say that this is an example of -- in your words from prior to the break -- as how the system is supposed to work in terms of notification about the impurity with genotoxic potential finding its way back to Teva?
A. Yes, I appreciate those words, Mr. Stanoch. Thank you.
Q. And you would expect this to be the case of how it should work for the discovery of genotoxic impurities in API that a manufacturer like Teva is buying generally, right?
A. Well, that's a very general statement. But I think in terms of the specifics here with a very difficult impurity to identify and measure, which can be there, it just needs a limit, Teva did something quite remarkable. They might --
Q. If -- I'm sorry. Go ahead.
A. I'm speculating, but they might have said to FDA, well, let's wait until we figure out what the limit should be, and, you know, they may not have needed to do a recall at all. But they acted highly responsibly at FDA's request.
Q. Uh-huh. Right. If ZHP came to be aware of a genotoxic impurity earlier than 2018, would you

Page 67

expect ZHP to inform Teva of that?
MS. LOCKARD: Objection. Outside the scope of his opinions. He is not here to give liability opinions about ZHP.
THE WITNESS: Yes, and I don't have any information on that, Mr. Stanoch, and I don't believe I cited anything about that question.
BY MR. STANOCH:
Q. In your answer a moment ago, you said Teva did something quite remarkable. Is it your opinion that Teva should have allowed their valsartan to be sold on the market while the FDA came up with interim limits?
A. I think that's a possible conjecture.
Q. So you are saying Teva could have -- strike that.
So you are saying Teva could have kept selling its valsartan with the NDMA in it until the FDA came up with interim limits?
MS. LOCKARD: Objection. Vague. Speculation.
THE WITNESS: Yeah, I am speculating, but I point out that it was unusual for FDA to ask a recall of an impurity which FDA says can be in a drug product and a drug substance. What was missing

Page 68

from the equation is the limits that FDA set in December 2018.
BY MR. STANOCH:
Q. Were there any acceptable limits for nitrosamines in valsartan API as of June 20, 2018?
A. Not that I'm aware of, no.
Q. Uh-huh. Right. Nitrosamines were -- there was -- strike that.
Right. There was no established acceptable limit for nitrosamines in any valsartan products prior to June 2018, correct?
A. Or any chemically synthesized drug in the U.S. market.
Q. Right. Because no one expected the nitrosamines to be in them, correct?
A. You are reiterating what FDA said. This was unexpected.
Q. Well, unexpected, you say that numerous times in your report, Doctor. We will get back to that.
But is it your opinion that without the interim guidelines, there were no guidances out there which would have indicated what level of nitrosamines were allowable in valsartan API or finished dose?

Page 69

A. That's my understanding.
Q. Right. So until the FDA caught ZHP, it was okay for any amount of nitrosamines to be in valsartan API; is that what you are saying?
MS. LOCKARD: Objection to the form of the question. Argumentative.
THE WITNESS: Yeah, no, I'm not saying that at all, but of course, you are dealing with an impurity which has a presence in food, and sometimes quite high levels. So FDA had just never crossed this bridge, nor had U.S. industry. Now, as a result of the events of the summer of 2018, they have crossed the bridge, so things are better.
BY MR. STANOCH:
Q. So you are saying until the FDA established acceptable intake limits for nitrosamines, it was okay whatever limit -- strike that.
You are saying that valsartan API could have nitrosamines in it until the FDA established interim acceptable limits?
A. Well, that's true now. You can have -- FDA will allow nitrosamine in drug products as long as they are within the acceptable intake limits. FDA is not saying that a product needs to have no

Page 70

nitrosamine impurities. That is not true.
Q. So it's your opinion that a drug manufacturer could have had any amount of nitrosamines in their drugs prior to the interim limits and that did not pose any concern?
A. I don't believe I said that anywhere in my report, but if you can point it out, Mr. Stanoch, I would be glad to comment.
Q. Well, I'm asking you now if that's your opinion, Doctor.
A. You want me to add that to my opinion in my report?
Q. Are you of the view that prior to the FDA's establishment of acceptable intake limits for nitrosamines, there was no prohibition on the amount of nitrosamines that could be in a drug product?
A. I think you are saying that correctly, because FDA didn't know how to measure for it, neither did industry. That all had to be worked out. And then once you could measure it, then you could begin, you know, following the recommendations of the 2015 guidance. And FDA did all that and came to a limit.
Now, you are sort of asking the question: What happens before you do all that work? And I

Page 71

guess the answer is, you know, that's how science progresses, that's how regulation progresses, and we're all the better for it now. I really can't speak to the past.
Q. Well, isn't it incumbent on a drug manufacturer to identify potential genotoxic impurities in its product?
A. You know, Mr. Stanoch, you keep asking these questions that are very general. Let me point out -- I don't know if you consider this germane, but let me say in the 1980s, before there was analytical technology, there were a whole bunch of impurities that neither FDA nor industry could even measure. What do you say about that?
I mean, are drugs more pure now, better controlled than they were in the 1980s? And my answer to that is yes. No question about it. You know, ICH and FDA worked together to bring that better control for what I will call usual impurities through the ICH documents.
And then later on, now, FDA came out with the guidance in 2015 that extended it to genotoxic impurities. And then the nitrosamine brought it all to the fore for a particular genotoxic impurity. So we're better off now.

Page 72

Q. Uh-huh.
A. Time marches on, regulation marches on. If you want to go back in the past and say everything was awful or not as good as it is now, I don't want to say that.
Q. Well, respectfully, Dr. Williams, things in the past were awful for some of the plaintiffs who got these drugs with a genotoxic carcinogen in it. So we are talking about that today, all right? Do you understand that?
MS. LOCKARD: I'm going to object to that. That's not a question --
MR. STANOCH: Withdrawn. I will withdraw it.
Q. You understand this case is about in part folks who took the drug, and they had nitrosamines in it, right?
A. I do understand that, and I would be loath to have an opinion about whether or how people were damaged by the presence of those nitrosamines. I'm not offering a toxicology or pharmacology opinion.
Q. Right. And it's your opinion, though, that until the FDA established the acceptable intake limits -- and when was that? The final guidance was, what, February 2021, I believe you say?

Page 73

A. No, but there were interim limits established in December 2018, and those carried forward into the guidance that appeared in September 2020, with an update in February 2021.
Q. Uh-huh. So it's your opinion that prior to December 2018, a drug can have any amount of NDMA in it with no regulatory consequence?
A. I wouldn't offer that opinion. I think it seems like a dangerous opinion to offer, and I'm surprised you state it.
Q. If a drug had 1,000 nanograms of NDMA in it in January of 2018, would that be appropriate?
MS. LOCKARD: Objection. Vague.
THE WITNESS: You know, I just can't comment on those kind of questions. You are getting into how does the FDA set limits for certain impurities. And, you know, it has to be done carefully and in the context of background, food impurities that are nitrosamine impurities. I just can't answer that question, Mr. Stanoch.
BY MR. STANOCH:
Q. Uh-huh. So you see no problem with a drug product that had a thousand nanograms of NDMA in it in January 2018?
A. I didn't offer that opinion.

Page 74

Q. I'm asking you, do you see any issue with a drug having a thousand nanograms of NDMA in it in January 2018?
MS. LOCKARD: Objection. Vague. Outside the scope of his class-certification report.
THE WITNESS: You know, and some of it, as you well know, Mr. Stanoch, relates to the amount of drug in the drug product and the duration of dosing. I mean, your hypothesis might be okay for a drug that's just taken once and never taken again as a single oral tablet.
BY MR. STANOCH:
Q. Uh-huh.
A. I just can't answer your question. There are too many factors that you are not specifying.
Q. Uh-huh. Uh-huh. So you can't tell me whether it was okay for any valsartan drug to have NDMA in it prior to the interim limits of December 2018?
MS. LOCKARD: Objection. Vague.
THE WITNESS: No, I do know that. FDA has said you could have nitrosamine in your drug product. They say that even now. The question is: What are the limits? And, you know, you can read about it in the guidance in terms of daily dose and

Page 75

duration of dose. That's how they come to these limits.
BY MR. STANOCH:
Q. Do you agree that there was no acceptable limit for nitrosamines prior to December 2018?
A. That's my understanding. The FDA did not have limits for the nitrosamine impurities before December 2018.
Q. So without an acceptable limit, then the limit is zero, isn't it?
A. No. No, no. I wouldn't say that at all. I don't know how you come to zero.
Q. Uh-huh. Well, the purpose of a limit is to say you can have this much of a substance in the drug, right?
A. Up to the limit.
Q. Correct. Up to the limit. Right. And so until that limit was determined, you can't have more than zero amount of a substance in it, can you?
A. No, no, I wouldn't agree with that at all.
Q. Well, so even without an interim limit, you are saying it was appropriate for a drug to have some amount of nitrosamine in it?
MS. LOCKARD: Objection. Asked and answered.

Page 76

THE WITNESS: Yes, I think that's what FDA would say. And remember, there can be many impurities in a drug substance that are below detectable limit that you just never know about. I mean, we're getting into hypotheticals that are beyond my report.
BY MR. STANOCH:
Q. Is it your opinion, sir, that without the interim guidelines, there were no guidances available which would have indicated what levels of nitrosamines could be present in valsartan?
MS. LOCKARD: Objection. Asked and answered.
THE WITNESS: Yes, that's my understanding, that those limits came in December 2018 from FDA.
BY MR. STANOCH:
Q. Uh-huh. So prior to December 2018, there was no guidance available to the industry about levels of nitrosamines in valsartan?
MS. LOCKARD: Objection. Asked and answered.
THE WITNESS: Yes, I -- do you want me to repeat my answer, Mr. Stanoch?

Page 77

BY MR. STANOCH:
Q. Please answer the question.
A. No, my understanding is I don't think there were specified limits for any nitrosamine impurity before December 2018.
Q. So I'm trying to understand your opinions, Doctor. So if there is not an established limit for a certain substance in a drug, then you can have that substance in the drug?
MS. LOCKARD: Objection. Vague. Also outside the scope of his expert report for class certification.
THE WITNESS: Yes, and I'm looking at my opinion where -- if we go to Page 46, where I look at my conclusions, I don't think I speak to the limit in that set of conclusions. But if you think I did, please draw my attention to it, Mr. Stanoch.
BY MR. STANOCH:
Q. Doctor, you reference interim limits throughout your report, don't you?
A. As provided by FDA in December 2018. I don't speak to them in any other context, just something that came from FDA.
Q. Uh-huh. So if there is not an established limit for a certain substance in a drug, you are

Page 78

saying that substance can be in the drug, no problem?
MS. LOCKARD: Objection. Vague. Asked and answered. Outside the scope of the class-certification expert report.
THE WITNESS: And that really isn't what I'm saying. I would say if somebody found a nitrosamine impurity in their drug product in 2018, they would properly follow the 2015 guidance and try to figure out a limit. But as I point out in my report, FDA did that for the entire industry. They didn't wait for a single manufacturer to do it.
BY MR. STANOCH:
Q. Uh-huh. If a manufacturer found a nitrosamine impurity in their drug product in 2018, they should have properly followed the 2015 guidance to try to figure out a limit, correct?
A. I think you are saying it correctly. I'll give a little bit more specification to your example. Let's say an NDA applicant who is building an application for consideration by FDA, if they found a nitrosamine impurity, they could follow the 2015 guidance and figure out a limit for it and then submit that to FDA, and FDA would review it and say, yeah, that limit is okay, or, no, we want you to do

Page 79

something different.
But in this case, FDA did that work for industry. So I would say industry now doesn't need to figure out their own limits. FDA has done that for them. And that's what is described in the guidance that I cite.
Q. Uh-huh. And you referenced a 2015 guidance. What are you talking about?
A. I think that's the M7 guidance.
Q. That's the ICH M7(R1) guidance, correct?
A. Yes. And I think I do cite that, so it should be in my materials considered.
Q. No, you do. I'm not -- issuing with that. I want to make sure I understood what you meant by 2015 guidance in your answer.
So I understand you are saying the FDA here set limits eventually for nitrosamines. But if a manufacturer had reason to believe its product contained nitrosamines, the appropriate course would have been for them to work towards establishing limits on their own prior to any FDA guidance, correct?
MS. LOCKARD: Objection. Outside the scope of his class-certification expert opinions.
THE WITNESS: Yes, I could imagine, and

Page 80

I'm speculating, that before FDA set limits, an individual company could have done it, and that might have been perfectly okay.
And even now, I suppose -- company or a consortium of company could try to convince FDA to set higher limits than the ones they set in December 2018. It's all subject to good data and a good scientific review.
BY MR. STANOCH:
Q. Uh-huh.
A. So I'm not debating what you are saying at all, Mr. Stanoch.
Q. Good. And I think we can agree, then, that under the ICH M7(R1) guidance from 2015, it would be incumbent on the manufacturer that discovered a genotoxic impurity to attempt to characterize, test it and potentially set limits on its own without regulatory action, correct?
MS. LOCKARD: Objection. Outside the scope.
THE WITNESS: Well, I would agree with your statement, except without regulatory action, because whatever the company would do would be subject to FDA review and approval.

Page 81

BY MR. STANOCH:
Q. Fair enough. So then, I guess, to clarify it, we agree, then, that under the ICH M7(R1) guidance from 2015, it would be incumbent on the manufacturer that suspected genotoxic impurity to attempt to characterize it, test it, and potentially set limits for it, and letting the regulatory body know?
A. And letting the regulatory body see the data and review it and approve it.
Q. That's fair. Let's take that same situation and say we're talking about an API manufacturer first, okay? You with me?
A. Okay.
Q. Okay. Right. Would you agree that under the ICH M7(R1) guidance from 2015, it would be incumbent on an API manufacturer that suspected a genotoxic impurity to attempt to characterize it, test it and potentially set limits for it, not only in connection with the regulatory body, but also customers purchasing that API?
MS. LOCKARD: Objection. This is getting far outside the scope of his class-certification expert report, Counsel. You are asking him about API manufacturers and their requirements. That's a

Page 82

liability opinion. He hasn't been retained for that issue, and specifically not for ZHP or any API manufacturers.

THE WITNESS: You know, and I would add, Mr. Stanoch, that if we're going to talk about it, it might be good to put that guidance on the screen and see exactly who it's directed to. Usually, when FDA creates a guidance with recommendations, they identify who it's intended for. And I'll be glad to review that with you if we could sort of find it.

It did not figure prominently in my report or my opinions because, as I have already noted, FDA did this for industry. I didn't have to look at what an industry drug-substance or drug-product manufacturer would have or should have done.

BY MR. STANOCH:

Q. We can look at the ICH guidance in a little bit, but sitting here right now, Doctor, is it your view that the ICH M7(R1) guidance applies only to finished-dose manufacturers, not API manufacturers?

A. No, I wouldn't say that. And if I looked at the nitrosamine guidance, I think when -- if we put that up, I think FDA is speaking to manufacturers of drug products and also drug

Page 83

substances.

Q. Uh-huh. All right. I'm going to repeat my question a little bit ago because you didn't answer it when you said you wanted to look at the MCH guidance.

So would you agree that under the ICH M7(R1) guidance from 2015, it would be incumbent on an API manufacturer that suspected a genotoxic impurity to attempt to characterize it, test it, potentially set limits for it, and to let the regulatory body and its API customers know?

MS. LOCKARD: I am going to object to this question. He said he's not going to answer it. He wants to look at the document. So you are asking him to interpret a document and you are refusing to provide it to him, so I have an objection.

We can take a break and get it if you want him to interpret it. It's also outside the scope of his expert opinion, however.

BY MR. STANOCH:

Q. Go ahead, Dr. Williams.

A. I'm sorry, Mr. Stanoch.

Q. Please answer the question.

MS. LOCKARD: If you can answer the question.

Page 84

MR. STANOCH: Enough, Counsel.

THE WITNESS: I would say at this point in time, Mr. Stanoch, I can't add anything more to what I have already said.

But I'm not going to disagree with you that, you know, a drug-substance manufacturer that suspects a genotoxic impurity would want to follow the guidance and, you know, make sure that it's a selling point to customers that we're controlling genotoxic impurities. That's a good drug substance.

BY MR. STANOCH:

Q. Uh-huh. Do you agree that nitrosamines are probable human carcinogens?

MS. LOCKARD: Objection. Outside the scope of his retention, his expert report, his disclosure.

THE WITNESS: Yeah, I'm certainly not offering opinion about that, but I have read the statements in the materials cited and some of the materials considered that would cause me to agree with what you said, Mr. Stanoch.

BY MR. STANOCH:

Q. Do you agree that nitrosamines are genotoxic?

A. Yeah, for purposes of discussions I will

Page 85

agree with that, Mr. Stanoch.

Q. Do you agree that nitrosamines are not an active ingredient in any FDA-approved drug?

MS. LOCKARD: Objection. Speculation.

THE WITNESS: To the best of my knowledge, Mr. Stanoch, I can agree with that.

BY MR. STANOCH:

Q. Uh-huh. Do you agree that the presence of nitrosamines even at trace level is considered unacceptable because these impurities are probable human carcinogens?

MS. LOCKARD: Objection. Outside the scope of his retention and his expert report on class certification. He is not here to testify about whether the drug is a potential human carcinogen. But if you want to waste your time asking him causation questions, have at it.

MR. STANOCH: Counsel, I don't need the colloquy. Thank you.

Please answer, Dr. Williams.

THE WITNESS: Would you restate the question, Mr. Stanoch? I'm sorry.

BY MR. STANOCH:

Q. Sure. Do you agree that the presence of nitrosamines even at trace level is considered

Page 86

unacceptable because these impurities are probable human carcinogens?
MS. LOCKARD: Same objection. It's outside of his scope, the class-certification expert report. He is not here to give a causation opinion.
THE WITNESS: But in answer to your question, Mr. Stanoch, no, I don't agree with that.
BY MR. STANOCH:
Q. Stand by. Stand by, sir.
You are familiar with the U.S. Pharmacopeia Association, right, the USP?
A. Yes, Mr. Stanoch, I am.
Q. Yeah, you mean you used to be affiliated with them, right?
A. I was an employee of USP between 2000 and 2014.
Q. Right. I'm going to mark another exhibit.
(Whereupon, Exhibit 4 was marked for identification.)
BY MR. STANOCH:
Q. You are going to have to look on your screen, unfortunately, Dr. Williams. I don't have a copy of this in the binder available.
Can you pull it up, or would you like me to share my screen? Exhibit 4.

Page 87

A. Oh, I'll rely on you to give me something that I can look at.
Q. Okay. Stand by, sir.
I'm now sharing my screen. This is Exhibit 4 in the public folder.
Do you see this, sir?
A. Could we open the box and get it out of the box?
MS. LOCKARD: Is it in the binder?
MR. STANOCH: It's not in the binder. I'm sorry.
THE WITNESS: I think you are showing me -- it looks like a PowerPoint; is that correct?
BY MR. STANOCH:
Q. Yeah, this is the -- correct. This is the cover page of a webinar in which Naiffer Romero of USP spoke on nitrosamine impurities?
A. Yeah, I don't see it very clearly. Can you expand it or --
MS. LOCKARD: Can you get it up out of the box?
THE WITNESS: I don't --
MR. STANOCH: It's not in the box, Counsel, I'm sorry.
THE WITNESS: Not in the box.

Page 88

MR. HARKINS: The exhibit share is what you are talking about.
MS. LOCKARD: The exhibit-share box is what I'm talking about.
THE WITNESS: Oh.
MR. HARKINS: Open the chat, Roger.
THE WITNESS: Oh.
(Whereupon, a brief discussion off the record.)
THE WITNESS: Okay. I'm opening the chat room, and --
MR. HARKINS: Hold on. Let me -- someone repaste the link to the exhibit share, please?
Sorry. Can someone please repaste the link to the exhibit share?
All right. Can you hear me in the room?
MR. STANOCH: We can hear you, Steve.
THE VIDEOGRAPHER: I might be able to retrieve it from the chat.
MR. HARKINS: Oh. I think that's it.
THE VIDEOGRAPHER: Okay. Yeah, you got it.
MR. HARKINS: You control it here on the separate screen, and you can scroll it down from there.

Page 89

THE WITNESS: Can I make it bigger?
MR. HARKINS: You should be able to zoom, yeah.
THE WITNESS: Okay. I'm looking at it, Mr. Stanoch.
BY MR. STANOCH:
Q. Okay. Great.
A. Please proceed.
Q. Sure. And you see the title page of this slide, it's a USP webinar presentation?
A. I think I do see that, yes.
Q. All right. And then there is -- I have an excerpt here, I have Slide 8 from that webinar on the next page, if you scroll down, sir. The slide says, "Background."
A. Okay. I'm looking at "Background."
Q. Great. And you will see that it's -- and the highlighting, by the way, is original in the document. I didn't modify this.
A. Okay.
Q. Do you see on the right it says, "Although nitrosamines are also present in some foods and drinking-water supplies, their presence in medicines, even at trace level is considered unacceptable because these impurities are probable

Page 90

human carcinogens." Did I read that right?
A. Yes, I think you read it correctly. And can you tell me the date of this document?
Q. It's 2020.
A. Oh, I see. All right. Thank you.
Q. Uh-huh. And do you agree with that statement from this USP presentation?
MS. LOCKARD: Objection. Asked and answered.
THE WITNESS: I would say what I rely on is FDA's guidance document, which it does say you can have nitrosamine impurities within acceptable limits.
BY MR. STANOCH:
Q. Uh-huh.
A. So I would not agree with this statement.
Q. Okay. And you see there in the middle, there is a fake Post-it that says, "Purpose of ICH M7"; do you see that?
A. Yes, I do see that.
Q. It reads, "Provide a practical framework that is applicable to the identification categorization, qualification, and control of mutagenic impurities to limit potential carcinogenic risk." Did I read that right?

Page 91

A. Yes, I think you are reading it correctly.
Q. And would you agree with that statement about the purpose of ICH M7?
A. Yes, that seems like a general statement, and I agree with it.
Q. Right. And that would have been the case with ICH M7 guidance prior to the FDA's first take at establishing interim limits for nitrosamines in December 2018, correct?
A. And although I didn't offer this as an opinion, I think FDA itself tended to follow the ICH M7 document, particularly with regard to the word "control." So when FDA is saying control, they are saying, we can put a limit on the NDMA impurity.
Q. Well, the guidance is to the industry to deal with impurities when they find them in their drug substance or their drug products, right?
A. Now, are you asking about M7?
Q. Yes.
A. Yes. And it's a general statement, but I think a specific example is the nitrosamine impurities, and that's what I alluded to in my report.
Q. Right. Well, you mention control in the context of the FDA setting limits. The point is,

Page 92

though, that a drug-substance or product manufacturer would follow ICH M7 guidance to identify, characterize, qualify, and control mutagenic impurities on its own, correct?
A. It could do. I mean, I'm not a toxicologist, but my understanding is that there could be many mutagenic impurities beyond the nitrosamine impurities that we're considering in this matter.
Q. Right. And it's the expectation that manufacturers on their own would work to identify, characterize, qualify, and control mutagenic impurities to limit potential carcinogenic risk, correct?
MS. LOCKARD: Objection. Outside the scope of his class-certification opinions.
THE WITNESS: Yes, and I'm certainly not debating with you the content of the M7 document, Mr. Stanoch. If you read statements from that, I would probably generally agree with your statements.
BY MR. STANOCH:
Q. Right. And you agree that it's the expectation that manufacturers would follow the ICH M7 guidance themselves, correct?
MS. LOCKARD: Objection. Asked and

Page 93

answered. Outside the scope.
THE WITNESS: With the exception of nitrosamine, where, if I may say so, FDA did the work of M7 on behalf of the entire industry.
BY MR. STANOCH:
Q. Well, prior to December 2018 there were no FDA interim limits, right?
A. That's true.
Q. Okay. But we had ICH M7 guidance, correct?
A. Yes.
Q. And the guidance set forth that manufacturers should identify, characterize, qualify, and control mutagenic impurities to limit potential carcinogenic risk, yes?
A. I'm not debating the words of the guidance, if that's your question. I agree with the words of the guidance.
Q. Well, I'm asking you about the application of the guidance, Dr. Williams, that even in the absence of the FDA interim limits in December 2018, was the expectation that a manufacturer would still attempt to identify, characterize, qualify, and control mutagenic impurities to limit potential carcinogenic risk?

Page 94

MS. LOCKARD: Objection. Vague. Outside the scope.
THE WITNESS: Yeah, I didn't really comment on this, Mr. Stanoch. Do you want me to speculate?
BY MR. STANOCH:
Q. I would like you to answer the question, Dr. Williams.
A. You know, the way I would say it, and I think I have already alluded to this previously, is, you know, an ANDA applicant generally follows the guidances I cited in my report.
And to the extent that they -- you know, when they get into qualifying an impurity, they may have to consider mutagenic or DNA-reactive impurities, and then they would turn to the M7 guidance. But that is certainly a case-by-case decision, and you would have to suspect the impurity was present and you would have to be able to measure it. So you are asking a very general question.
Q. And the ICH M7 guidance is not confined to ANDA applications, correct?
A. That's my understanding. Again, if you are going to ask me questions about it, it would probably be best if I could see it.

Page 95

Q. Well, we will get to specific parts of it, but -- your understanding that the ICH M7 guidance applies to the life of a drug from application through commercialization, correct?
A. Again, you know, I feel very uncomfortable answering questions about a document that I haven't seen and that I cite in my report, but I would say it was not particularly important to my opinions.
But again, you know, I'll be glad to walk through it with you, Mr. Stanoch. I don't think it is particularly appropriate for my opinions or important to my opinions, but again, I'm certainly here to be responsive to your questions.
Q. Right. And you agree that the ICH M7 guidance applies throughout the life of a drug, correct?
A. I don't believe I said that. I think what I said is if we're going -- if you are going to ask me that question, I feel like I need to see the guidance.
Q. You can't tell me anything about the ICH M7 guidance general applicability without looking at it?
A. I think, yes, I'm saying that. I would be hesitant to make statements about the guidance along

Page 96

the lines of your questioning.
Q. So you can't tell me one way or the other about whether the ICH M7 guidance applies throughout the life of a drug?
MS. LOCKARD: Objection. Asked and answered.
He said if you are going to ask him questions about the application and interpretation of the guidance, he wants to have it in front of him, which is a fair request.
BY MR. STANOCH:
Q. You can answer the question, Dr. Williams.
MS. LOCKARD: Objection. It's argumentative.
THE WITNESS: I prefer not to answer the question without seeing the guidance.
BY MR. STANOCH:
Q. And which guidance do you want to see, Doctor?
A. M7.
Q. What version?
A. The current version.
Q. What year?
A. I think it's 2015.
Q. Show me where it is in your reliance

Page 97

materials and report, which version you want.
MS. LOCKARD: Let me just put an objection on the record. You are asking him questions about a guidance that you haven't identified. He is asking to see the guidance that you were questioning him about. If you want to question him about a document, identify it. Now you are telling him to --
MR. STANOCH: Counsel, enough. Enough, Counsel. Counsel, enough.
(Overlapping speakers.)
MR. STANOCH: I'm asking him to tell me the document he wants. I'm asking him to tell me what document he wants. I'm trying to comply with his request, Counsel. Please, let him tell me what he wants to see. Thank you.
We have lost Dr. Williams. Dr. Williams, we can't see you.
MS. LOCKARD: We're on break. We can go off the record. You can keep running.
MR. STANOCH: Wait a minute. Wait a minute. Wait a minute. Wait a minute. I am not agreeing to go off the record. I have a pending question to the witness to tell me what document he said he needs to see. I am not agreeing to go off

Page 98

the record.
Q. Are you going to answer the question, Dr. Williams?
MR. STANOCH: Or, Counsel, are you going to instruct him not to answer it?
Well, let it be noted that despite the nonagreement and the pending question, both the witness and counsel have gone off.
Let's keep running.
THE WITNESS: I have been instructed by counsel to come back, Mr. Stanoch, and now I'm trying to look for the guidance that you are alluding to.
MR. STANOCH: Thank you.
THE WITNESS: And I would say we can look, if you agree, to the guidance for industry genotoxic -- the other one -- I would really appreciate it if you would pick the guidance because you are talking about it. But yes, here it is.
I have been handed it in a copy. M7, Revision 1, Addendum to ICH M7. Now, that makes me a little nervous because it's an addendum, and it makes me wonder, where is the M7(R1)? But if we can look at M7(R1), I'll be glad to answer questions about it if I can.

Page 99

BY MR. STANOCH:
Q. I'm --
A. Can you proceed, Mr. Stanoch?
Q. Well, I want to make sure we have the right documents in front of us, and I have to mark it, Dr. Williams. So why don't you tell me the date of the document you are looking at?
A. Well, what I have been handed is M7(R1), dated March 31st, 2017, and then a M7(R1) addendum, so it's lot of paper and I'm looking at two documents.
MS. LOCKARD: And for the record, I still don't know what it is that your question is asking about, so we are trying to print whatever we think you are asking about, but you have refused so far to identify -- counsel has refused to identify the specific guidance that he is asking the doctor to interpret, so --
THE WITNESS: Okay. I'm prepared to answer questions. Did you get the dates of the documents I'm looking at? The M7, Revision 1, is March 2017.
MS. LOCKARD: Can you hear us?
MR. STANOCH: Yeah, I'm trying to pull up the version that you have in the hard copy for the

Page 100

benefit of all of your colleagues on Zoom. Well, that's going to take me time.
Q. Doctor, I can pull up the March 2018 guidance. You want to work with that for now? Or would --
A. And I also think it would be important to go to my report where I reference this document. Let me see if I can find that.
MS. LOCKARD: And while he is doing that, Exhibit 4 was the USP PowerPoint. It looks like there are only two pages of that. Do you have the -- are you making the full PowerPoint the exhibit?
MR. STANOCH: Those are excerpts from the webinar. We will mark the entire webinar.
Q. Well, Doctor, let's see if we can cut through this a little bit, shall we? You agree, do you not, that ICH M7 guidance has been in effect -- has been effective in different forms for quite some time, yes?
A. I can agree with that, Mr. Stanoch, please, if the --
Q. Sure. Sure. And why don't we get a ballpark. I mean, can we say that at least since 2003 there has been some form of ICH M7 guidance?

Page 101

A. You know, I'd hesitate from that, but for purpose of a discussion let me agree so that we can go forward.
Q. I appreciate that. I won't hold you to the particular date. I was just trying to pick a date that we could just move forward from. So -- and we can agree, can we not, that there has been revisions and addenda to the M7 guidance over time, correct?
A. Okay. Let me agree.
Q. And would you agree that even in the absence of FDA interim limits for nitrosamines, there was an expectation that a manufacturer would adhere to the ICH M7 guidance concerning genotoxic impurities, whatever the status of that guidance was at the particular time?
MS. LOCKARD: Objection. These are liability opinions and outside the scope of his report.
THE WITNESS: Yeah, I am very hesitant with your general statements, but again, I won't contest them so we can move forward. Go ahead, Mr. Stanoch.
BY MR. STANOCH:
Q. I'm a little unclear what you mean by

Page 102

don't contest them. Does that mean you will agree with that question?
MS. LOCKARD: Objection. Vague.
THE WITNESS: You know, it would be much -- can you restate the question?
BY MR. STANOCH:
Q. Sure. Would you agree that even in the absence of FDA interim limits for nitrosamines, there was an expectation that a manufacturer would adhere to the ICH M7 guidance concerning genotoxic impurities as that guidance stood at the particular time?
MS. LOCKARD: Objection. Vague. Outside the scope of his expert report.
THE WITNESS: Yes, it's not any opinion I offered, but I won't debate what you are saying, so I can agree with it, Mr. Stanoch.
BY MR. STANOCH:
Q. Fair enough. And do you agree that the ICH M7 guidance includes nitrosamines in the cohort of concern? And if you need to look at the version in front of you, that's fine, and we could mark it later.
A. I don't know where I see nitrosamines here, and I didn't look for it.

Page 103

Q. All right. Let --
A. Can you point it out where you see it, Mr. Stanoch?
Q. Sure. Put that aside, then. Let's put it a different way. Are you aware that the FDA has stated that N-nitroso compounds are identified as a cohort of concern in ICH M7 guidance?
MS. LOCKARD: Objection. Outside the scope of his expert report.
THE WITNESS: Yeah, I see no reason to deny what you are saying, so I'll agree with it to continue the discussion, Mr. Stanoch.
BY MR. STANOCH:
Q. Thank you. I appreciate that, Doctor.
And a substance that falls within the ICH cohort of concern should be controlled, correct?
MS. LOCKARD: Objection. Falls outside of the scope of his class-certification opinions.
THE WITNESS: You know, I could probably agree more readily if you could show me where you are reading in the guidance. But again, for purposes of the discussion, I won't debate what you are saying, Mr. Stanoch. I'm sure you are reading it correctly.
MS. LOCKARD: I wouldn't assume that he is

Page 104

reading anything correctly.
THE WITNESS: No, okay.
All right. Well, I'm a little hesitant about answering, Mr. Stanoch.
MR. STANOCH: Then stand by for an exhibit, sir.
I'm going to mark the next exhibit, sir.
(Whereupon, Exhibit 5 was marked for identification.)
BY MR. STANOCH:
Q. Exhibit 5. This is actually Tab 2 in your binder. You can take the binder out of the box we sent you as a courtesy.
MS. LOCKARD: Hold on. We are opening the box. There is one black binder in here. Tab 2?
MR. STANOCH: Yes, please.
MS. LOCKARD: Okay.
BY MR. STANOCH:
Q. Tell me when you have that, Doctor.
A. I think I'm looking at it. Tab 2, it is a letter from FDA to -- I don't see who it's to. But it looks to be about a five-page letter.
Q. Right. It's a general advice letter from the FDA. You see that in the upper right, "General Advice"?

Page 105

A. I do see that.
Q. Uh-huh. And do you see --
MS. LOCKARD: There is no Bates number, for those on the call.
BY MR. STANOCH:
Q. Would you look at the last paragraph of the first page, sir?
A. Last paragraph, first page.
Q. It begins, "Nitrosamine compounds." Do you see that?
A. Wait a minute. Oh, "Nitrosamine compounds." Yes, I'm with you, Mr. Stanoch. Go ahead.
Q. Wonderful. Why don't you read for us the first few sentences of that paragraph?
A. "Nitrosamine compounds are potent genotoxic carcinogens in several nonclinical species and are classified as probable human carcinogens by the International Agency for Research on Cancer. In fact, 'N-nitroso' compounds are identified as a 'cohort of concern' in internationally" recognized "guidance, ICH M7," and then it states the name.
Should I stop there?
Q. Keep going. Slowly, please, for the court reporter.

Page 106

A. "ICH M7 recommends that known mutagenic carcinogens, such as nitrosamines," to "be controlled at or below the acceptable cancer risk level. Due to their known potent carcinogenic effects, and because it is feasible to limit these impurities by taking reasonable steps to prevent or eliminate their presence, FDA has determined that there is no acceptable specification for nitrosamines in ARB API and DP."

Q. That's fine. Okay. And, oh, actually, why don't you read the one more sentence?

A. "Therefore, FDA advises that nitrosamines should be absent (not detectable as described below) from ARB API and ARB drug products."

Q. Okay. Thank you.

So, first of all, were you aware of this general advice letter from the FDA prior to right now?

A. No.

Q. Okay. Second of all, do you agree with the FDA's statement in this letter that nitrosamine compounds are potent genotoxic carcinogens?

MS. LOCKARD: Objection. Outside the scope of his class-certification opinions. He is not here to give a causation opinion.

Page 107

THE WITNESS: And I know I'm not supposed to ask questions, but I don't see a date on this letter. Is there a date?

BY MR. STANOCH:

Q. It doesn't appear that it has a date on it.

A. And also, if I may say so, I think this conflicts with the FDA guidance on nitrosamine impurities, but we can have that conversation if you wish.

But anyway, back to you, Mr. Stanoch. Am I answering your questions about this document?

Q. Well, not yet. The question was: Do you agree with the FDA's statement that nitrosamine compounds are potent genotoxic carcinogens?

MS. LOCKARD: Objection. Outside the scope of his class-certification opinions. He is not here to give a causation opinion.

THE WITNESS: Yes, and I'm not going to debate the wording in this letter. It seems like a formal letter from the agency, and I'm not in a position to disagree with FDA on this point.

So please continue, Mr. Stanoch.

BY MR. STANOCH:

Q. I certainly will. Thank you, Doctor.

Page 108

And the next sentence, do you agree with the FDA that N-nitroso compounds are part of the cohort of concern under ICH M7 guidance?

A. Yes, I see the words, and I think you are reading them correctly.

Q. And do you agree with that statement, regardless of whether I read it correctly?

MS. LOCKARD: Does he agree that it -- right. Objection. Vague.

THE WITNESS: I see no reason to disagree with the words in this letter.

BY MR. STANOCH:

Q. Perfect. And do you agree, then, that as part of the cohort of concern, nitrosamines should be controlled?

A. Yes, I can agree with that.

Q. All right. And do you agree generally that nitrosamines can be controlled?

A. Yes, I think FDA documented that in its December 2018 statement.

Q. And do you agree that nitrosamines can be avoided entirely?

A. You know, that's sort of a case-by-case question.

But what is perplexing me about this

Page 109

letter is I think the FDA guidance says you can have nitrosamine impurities as long as they stay within the acceptable intake limits.

Q. Uh-huh.

A. So I see a dissonance between this letter and the FDA guidance.

Q. Uh-huh.

A. But please continue.

Q. And you say "a case-by-case basis." Do you mean by that that it would be on a particular manufacturer to assess whether nitrosamines could be avoided entirely in its manufacturing process?

A. Yes, I agree with the way you stated that. Thank you.

Q. Uh-huh. Yep. And were you aware prior to seeing this letter that at one point the FDA said that it had determined that there is no acceptable specification for nitrosamines in ARB API and DP?

A. Well, as I say, I think that's not what the guidance says, but I see where it says it here in this letter.

Q. Uh-huh. You keep saying "guidance." Which guidance do you mean specifically?

A. It was the nitrosamine impurities guidance that I cite in my report. It came out in September

Page 110

of 2020, and then it was updated in February of 2021.
Q. Uh-huh. So at the time this FDA general advice letter was put out, it was the FDA's view that there is no acceptable specification for nitrosamines in ARB API and DP, correct?
A. Yes, and we don't quite know when because we can't see a date on this letter.
Q. Well, I believe the letter was from sometime in 2019.
MS. LOCKARD: Objection to counsel testifying.
BY MR. STANOCH:
Q. Assume the letter was from 2019, Doctor, okay?
A. Okay. I'm willing to make that assumption. It may have come out, then --
Q. Great.
A. It may have come out, then, before the first iteration of the draft September 2020 guidance, and therefore the guidance superseded this document.
Q. Sure. Then --
A. That would resolve my dissonance.
Q. And that may be the sequence of events,

Page 111

Doctor. But at the time this letter came out, right, the FDA had determined there is no acceptable specification for nitrosamines in ARB API and DP, right?
A. I see the wording in the letter. I don't disagree with the way you are stating the wording. And I'm willing to make the assumption it came out sometime in 2019.
Q. So then, at the time of this letter, there should be no nitrosamines in any valsartan API or drug product, correct?
MS. LOCKARD: Objection. Vague. Foundation.
THE WITNESS: Well, I think FDA is even saying in this letter that they provided interim acceptable limits for nitrosamine impurities in ARBs. So I don't know how to kind of piece together what it's saying here versus, well, the other realities of their December 2018 decision and the guidance that I cited in my report.
BY MR. STANOCH:
Q. Uh-huh. The FDA goes on to say that they used the interim limits only to guide immediate decision-making for the product recalls. Do you see that?

Page 112

MS. LOCKARD: What paragraph are you looking at?
MR. STANOCH: Same one.
THE WITNESS: Uh-huh. Well, we can keep on looking at this letter. Is there a question pending, Mr. Stanoch?
BY MR. STANOCH:
Q. There was. The FDA goes on to say they used the interim limits only to guide immediate decision-making for the product recalls. Do you see that?
A. I do see that.
Q. Uh-huh. And were you aware of that prior to today?
MS. LOCKARD: Objection. Vague.
THE WITNESS: And this is the first time I have seen this letter.
BY MR. STANOCH:
Q. Okay. Let's put that aside for now, Doctor.
A. Okay. Thank you.
Q. Why don't you flip to Tab 3 in your binder. It will be introduced as Exhibit 6.
(Whereupon, Exhibit 6 was marked for identification.)

Page 113

BY MR. STANOCH:
Q. Tell me when you are there, Doctor.
A. I'm there. I see it. M7(R1). Is that what we're talking about, March 2018?
Q. Yes, sir. We're on the same document. That's a good step. So are you familiar with this document?
A. I'm aware of it. I did not study it closely for my report.
Q. That's okay. But you understand that it's the ICH guidance as of March 2018, correct?
A. Yes, I do. And then the one I had printed out for me before was dated 31 March 2017.
Q. Right. And I don't have a copy of exactly what you were handed. We can get it.
But this goes back to our point that the guidance might have went through various iterations over time generally, right?
A. Yes, exactly. That's how the ICH guidances work. So I'm prepared to consider this with you, Mr. Stanoch.
Q. That's great. So why don't we turn to page 5 of this document, sir?
A. All right.
Q. And tell me when you are there.

A. I'm there. Where it says, "General Principles"?
Q. Yes, sir. And then you see the paragraph in the middle, "A Threshold of Toxicological Concern"?
A. I do see that.
Q. Uh-huh. And do you see at the end that this March 2018 guidance states, "This group of high potency mutagenic carcinogens, referred to as the cohort of concern, comprises aflatoxin-like-, N-nitroso-, and alkyl-azoxy compounds," correct?
A. Yes, I do see that.
Q. All right. And N-nitroso compounds, those would include the NDMA and NDEA nitrosamines that you discuss in your report, correct?
A. I think you are saying that correctly. Thank you, Mr. Stanoch.
Q. And then what is your understanding of cohort of concern, sir?
A. As the words say here, it's a group of high-potency mutagenic carcinogens that comprises the three -- excuse me, Mr. Stanoch -- that comprises the three types of compounds stated in the sentence. A cohort of concern, apparently they are trying to classify some particularly mutagenic

carcinogens, as stated here in the sentence.
Q. And the purpose of that is to alert industry that limits for the cohort of concern might be much lower than the threshold of toxicological concern that might otherwise be defined per the guidance, right?
MS. LOCKARD: Objection. Vague. And outside the scope of his testimony.
THE WITNESS: Yeah. And you are beginning to ask me questions that I would call pharmacology/toxicology questions.
I can read the sentences here and agree with them, Mr. Stanoch. For example, it says, "Some structural groups were identified to be of such high potency," and then the sentence continues. And these high potency are referred to as a cohort of concern, and then it lists the three compounds that fall into the structural categories that we have already discussed.
BY MR. STANOCH:
Q. Uh-huh. And then the threshold of toxicological concern, what does that relate to?
MS. LOCKARD: Objection. Vague. Outside the scope.
THE WITNESS: Well, if we go back to the

beginning of the paragraph, it says, "was developed to define an acceptable intake for any unstudied chemical that poses a negligible risk." So I guess if it is below the threshold, the risk is negligible, but if it is above, you begin to have some concern. Please correct me if --
BY MR. STANOCH:
Q. Right. I apologize. Are you done, Doctor?
A. Yes, I think I am. Thank you, Mr. Stanoch.
Q. Yes. And just following along, you see later in that paragraph it says, "For application of a TTC in the assessment of acceptable limits of mutagenic impurities," and the sentence continues. Do you see that?
A. I do.
Q. Right. And the purpose of the TTC was to assess acceptable limits of impurities in drug substances, correct?
MS. LOCKARD: Objection. Outside the scope of his expert opinion. You are asking him what the purpose of the TTC was. This is not part of his class-certification report.
THE WITNESS: Yeah, and -- the only thing

I can do is read the words and sort of say I have a general understanding of what they are saying. I'm certainly not a pharmacologist-toxicologist.
BY MR. STANOCH:
Q. I'm not asking for a pharmacology or toxicology opinion, Doctor. I'm asking your understanding in the context of a report where you talk about thresholds of limits that may or may not have existed.
We're looking now here at the ICH guidance, the March 20th, 2018, version, and it's talking about acceptable limits of mutagenic impurities, right?
A. But I still don't see limits. Am I missing limits?
Q. Well, the whole thrust is talking about assessment of acceptable limits, is it not?
A. I think it's talking about it generally, but when I spoke about it in my report, I was talking specifically about the limits that FDA created in December 2018 and nothing more.
Q. Right. And what I'm getting at, Doctor, is: Prior to the FDA's interim limits, there already was industry guidance on acceptable limits of mutagenic impurities, correct?

Page 118

MS. LOCKARD: Objection. Outside the scope of his opinions.
THE WITNESS: If you are talking about this document, I would certainly agree with you.
BY MR. STANOCH:
Q. Great. And you would agree for any other iteration of this M7(R1) guidance prior to this one that spoke of acceptable limits of mutagenic impurities as well, correct?
A. Well, that's a broad statement, but again, let me agree for purposes of discussion.
Q. I appreciate that. And then let's flip to page 14. Let me know when you are there, sir.
A. Okay. I'm there.
Q. And do you see Section E, sir?
A. I do.
Q. Right. And do you see there is three bullets under Section E?
A. I do.
Q. And the third bullet is talking about the cohort of concern impurities again, fair?
A. I see that, yes.
Q. And it notes, "If these compounds are found as impurities in pharmaceuticals, acceptable intakes for these high-potency carcinogens would

Page 119

likely be significantly lower than the acceptable intakes defined in this guidance."
Did I read that right?
A. I can agree with your reading of the words.
Q. Uh-huh. Right. And then you see it further says, "Although the principles of this guidance can be used, a case-by-case approach using," for example, "carcinogenicity data from closely related structures, if available, should usually be developed to justify acceptable intakes for pharmaceutical development and marketed products."
Did I read that correctly?
A. I think you are reading it correctly, yes, no question about that.
Q. I appreciate that, Doctor.
And so what the guidance we're looking at here is saying is that for the cohort of concern impurities, which includes the nitrosamine compounds, at least as of the date of this guidance of March 2018, that acceptable intake limits for it should be developed for both the development and marketing of pharmaceutical products?
A. Well, I agree with you. I think that's

Page 120

what we're talking about, what are the acceptable intake limits. And I think FDA has -- they provided those in December 2018. That's what I stated in my report.
Q. You --
A. You know, as long as we're sort of looking at this ad hoc document that I did not study or cite in my report other than to notice its availability, Mr. Stanoch, I might draw your attention to the first bullet on this page, where it says, "Higher acceptable intakes may be justified when human exposure to the impurity will be much greater from other sources, e.g., food." Now, of course that's exactly the case with nitrosamines.
Q. Well, thank you for the gratuitous statement, Doctor, but let's talk about that.
All three of these bullets we are looking at, flexibilities in approaches, they are suggesting to manufacturers to conduct a case-by-case approach to come up with acceptable intake limits for products, correct?
A. Yes, and in the case of nitrosamines, in the current matter, FDA did that for manufacturers, as the prior letter you showed me noticed, in December 2018.

Page 121

Q. Right. Well, prior to the FDA's interim limits for nitrosamines in December of 2018, there already was industry guidance, was there not, that manufacturers should be conducting their own assessments to potentially set limits for impurities such as nitrosamines?
MS. LOCKARD: Objection. Outside the scope of his class-certification opinions.
THE WITNESS: Yes, and remember, we're dealing with a situation where FDA said this was unexpected, they didn't know how it occurred. They had many other caveats that indicated, if you will, their surprise that came about in the summer of 2018. These are very low-level impurities, and you would have to suspect them and then have analytical capability to identify them, notwithstanding all the words in this guidance.
So I'm glad to walk through the guidance with you. I think it's an interesting and important guidance, Mr. Stanoch, but it really only is tangentially related to my report.
BY MR. STANOCH:
Q. So it's not important to your opinions that there already was industry guidance on how to address levels of nitrosamines in drugs prior to the

Page 122

December 2018 FDA interim guidance?
MS. LOCKARD: Objection. Outside of the scope of his opinions. That's not what he was retained, that's not what he discussed in his expert report.
THE WITNESS: Yeah, I'm listening to the two counsel, and I think the way you both said it is correct. I was considering other factors and information that I cited in my report that led to my opinions, and I certainly haven't changed my opinions as a result of the review of this document.
BY MR. STANOCH:
Q. Okay. Are you aware of any Novartis Diovan product sold in the --
(Reporter clarification.)
MR. STANOCH: No problem. Let's start over.
Q. Are you aware of any Novartis Diovan product sold in the United States that contained NDMA?
A. I am not.
Q. Are you aware of any Novartis Diovan product sold in the United States that contained NDEA?
A. No, I am not.

Page 123

Q. You are aware, are you not, that Novartis detected NDMA in ZHP's valsartan API prior to June 20th, 2018, correct?
A. You know, I have heard statements to that effect from counsel, but I don't think I have ever seen any documents for it. I don't think a document exists on my materials-considered list, and I certainly didn't cite anything like that in my report.
Q. Uh-huh. Can you tell us how --
A. But I would be glad to look at such a document if you have it, Mr. Stanoch.
Q. Uh-huh. Can you tell us how Novartis was able to identify NDMA in ZHP's valsartan API prior to June 20, 2018?
MS. LOCKARD: Objection. Outside the scope of his expert opinions on class certification. Lacks foundation. Speculation.
THE WITNESS: You know, I'm not, Mr. Stanoch. I just don't have any documents to speak to that. I would be glad to look at them if you have them.
BY MR. STANOCH:
Q. Uh-huh. Can you tell us how Novartis was able to identify NDMA in ZHP's valsartan API prior

Page 124

to June 20, 2018, but Teva could not?
MS. LOCKARD: Objection. Outside the scope of his expert opinion on class-certification issues. Vague. Lacks foundation. Argumentative.
THE WITNESS: Again, Mr. Stanoch, I just have not seen any documents to that point. If you can point to them in my materials considered, I would be glad to look at them with you.
BY MR. STANOCH:
Q. Uh-huh. Well, you tell me, Doctor, did you look at any materials that identify how Novartis was able to discover NDMA in ZHP's valsartan API?
MS. LOCKARD: Objection. Outside the scope of his class-certification opinions. Lacks foundation. Speculation.
THE WITNESS: And my apologies, Mr. Stanoch. I thought I had answered that question. I have not seen any documents, anywhere, that speak to Novartis' testing of any products for nitrosamines.
BY MR. STANOCH:
Q. Can you tell me what methods Novartis used to detect NDMA in ZHP's valsartan API?
MS. LOCKARD: Objection. Outside the scope of his class-certification opinions. Lacks

Page 125

foundation. Speculation.
THE WITNESS: No, I cannot, Mr. Stanoch.
BY MR. STANOCH:
Q. You cannot tell me why Novartis would have a method for detecting NDMA in ZHP's valsartan API, can you?
MS. LOCKARD: Objection. Outside the scope of his class-certification opinions. Lacks foundation. Calls for speculation.
THE WITNESS: No, I can't, Mr. Stanoch.
BY MR. STANOCH:
Q. Why would -- strike that. Start over.
Why would Novartis be testing ZHP's valsartan API for NDMA in the first place?
MS. LOCKARD: Objection. Outside the scope of his class-certification opinions. Calls for speculation. Lacks foundation.
THE WITNESS: I just have no idea, Mr. Stanoch. It would be guessing, and I could only guess.
BY MR. STANOCH:
Q. Well, there is no specification in the Diovan monograph, for example, for nitrosamines, right?
A. When you say "Diovan monograph," I assume

Page 126

you are talking about the USP monographs for valsartan API and valsartan drug product, and if that's what we are talking about, Mr. Stanoch, there are no tests for nitrosamine in those monographs.
Q. That would be for both the branded Diovan product as well as generic valsartan products, correct?
A. I think you are saying that correctly, Mr. Stanoch, that USP doesn't distinguish between manufacturers. The monographs are supposed to apply to all manufacturers of the named article.
Q. When you refer in your report to compendial requirements, what do you mean?
A. Well, in brief, I think, as we have already discussed, we're talking about the monographs, in this case, for valsartan drug substance and valsartan drug product.
Q. Right. And you have looked at a couple of monographs for valsartan, correct?
A. Yes, I think they were part of the information I looked at, and I think they are in my materials considered. And I'm glad to talk about them if you wish, Mr. Stanoch.
Q. Of course. Would you agree that compendial requirements includes the general USP

Page 127

chapters?
A. Yes, the way I would say it is there is general notices, which appear at the front of USP and are generally applicable, and then a monograph can reference general chapters that give detailed information about a particular test or procedure.
Q. Got it. So it's fair to say, then, that compendial requirements includes a drug monograph, general notices and requirements, and conformance to standards?
A. Yes. And if a monograph references a general chapter, that would be part of the monograph.
Q. And those also would include notices on impurities, correct?
A. My sense is that impurities are a universal test and should be present in most, if not all, drug-substance and drug-product monographs, and that would certainly be true of the valsartan monographs.
Q. Uh-huh, uh-huh. And we talked earlier that the FDA nitrosamine impurities guidance, I think you said, was updated last September 2021?
A. Well, it appeared first in draft in September '20, and then it was updated in

Page 128

February 2021.
Q. I apologize. That's correct. I agree with you there.
I'm going to mark an exhibit. Stand by, sir.
(Whereupon, Exhibit 7 was marked for identification.)
BY MR. STANOCH:
Q. Stand by.
Okay. Exhibit 7, sir, has now been marked. It also should be Tab 17 in your binder if you would like to look at the hard copy. Tell me when you are there.
A. Yes, I'm looking at it, Mr. Stanoch. I'm --
Q. Excellent. And this appears to be a copy of the valsartan USP monograph printed January 28th, 2022. Do you see that?
A. Yes, and -- okay. Yes, I'm prepared to discuss.
Q. Very good. So this would be an example of a USP monograph that we were talking moments ago, correct?
A. Exactly.
Q. All right. And this monograph is for

Page 129

valsartan, correct?
A. Yes.
Q. And the date of this is current official from last month, so this was after the FDA's last turn of its nitrosamine impurities guidance in February 2021, right?
A. I'm not sure I understood what you said. It says, "Official Date: Official as of" May 1, 2020. Are we looking at the same thing?
Q. Right. And "Official Status" right above that, sir, "Official Status: Currently Official on 28-Jan-2022." You see that?
A. I do, and that would be about a year after the nitrosamine guidance.
Q. I can agree with that. And do you see any mention of a test for nitrosamines in this valsartan monograph?
A. All right. Now hold on just a sec. Okay. When we get to "Impurities," I see, "Procedure 1: Limit of Valsartan Related Compound A." "Procedure 2: Limit of Valsartan Related Compound B, Valsartan Related Compound C, and Other Related Compounds." And that's all I see. I do not see tests for nitrosamine impurities.
Q. Do you see any reference to acceptable

Page 130

limits for nitrosamines in this monograph?
A. I do not.
Q. Do you see any mention whatsoever of nitrosamines in this valsartan monograph?
A. I don't believe -- I do not, Mr. Stanoch. Please correct me if you think I'm wrong.
Q. No, I think you are correct. I just wanted to make sure we're on the same page. I don't see any mention of nitrosamines whatsoever in this monograph, and it sounds like you agree with me, correct?
A. Yes.
Q. So if a drug manufacturer made valsartan exactly per this monograph, they wouldn't necessarily be doing anything to test or control for NDMA, would they?
A. If they just followed the monograph, I think I would agree with you.
Q. Right. Following a monograph alone would not mean that a product was complying with the FDA's nitrosamine impurity guidance and limits, correct?
A. Oh, I'm sorry. I'm hesitating a little bit because you alluded back to the nitrosamine impurities guidance.
Q. Well, I'll withdraw the question and I'll

Page 131

phrase it again. Following this monograph alone to manufacture valsartan would not have any specified way of identifying and controlling nitrosamines, correct?
A. I think you are -- yes, I agree with you, Mr. Stanoch.
Q. Uh-huh. So the fact that a drug complies with a USP monograph alone does not mean the drug is free of any nitrosamine impurities?
A. Yes, I think you are right. That ability to control nitrosamine would come up in the application to FDA and the FDA review. It would not be in the USP monograph.
Q. Okay. And the USP is not responsible for identifying genotoxic impurities in drug product or drug substance, right?
A. No, I agree with your -- that to me is more a regulatory matter.
Q. All right. USP believes companies are responsible for identifying and assessing genotoxic impurities in their drug product or substance, correct?
A. Yes. It's up to the manufacturer working with FDA to detect -- I'm trying to think of the string of words -- report, identify, qualify, and

Page 132

that specifically applies to a genotoxic impurity such as nitrosamines.
Q. Uh-huh. Uh-huh. As of the date of this valsartan monograph, January 28, 2022, if a manufacturer followed it exactly, it would have no way of testing and identifying nitrosamines in the product, correct?
MS. LOCKARD: Objection. Vague.
THE WITNESS: I think I'll agree with you, Mr. Stanoch.
BY MR. STANOCH:
Q. So whether a product was made according to a USP monograph or not does not definitively speak to whether the product contains nitrosamines, correct?
A. Well, remember, you don't make a product according to a monograph. This is a monograph that has tests, procedures, acceptance criteria, that if you -- I'm trying to get into the USP understanding -- if your drug substance conforms to all these tests, then you can confirm that you have valsartan.
Now, as you are discussing, and I agree with you, it doesn't say, does your valsartan have nitrosamine impurities that are adequately

Page 133

controlled? That is a separate matter that is adjudicated by FDA.
Q. Uh-huh. And USP general notices and requirements may also guide a manufacturer on how to identify nitrosamine impurities, correct?
A. Well, yeah, there may be some statements in there that are very general statements, for example, that you have to follow GMPs, and GMPs may say, yes, you have to think about a genotoxic impurity.
And I have heard it said, although I haven't seen it, Mr. Stanoch, I have heard that USP has general chapters on how to measure nitrosamine impurities.
Q. Uh-huh.
A. But I can't confirm that. I just heard it. Maybe you are aware of it and I'm not.
Q. And is that discussed anywhere in your report, sir?
A. No, not at all. And as a matter of fact, this monograph is not discussed in my report. I think I am talking about monographs that were official at the time of the 2018 time period.
Q. So, well, we can pull those up too, Doctor. But if someone followed the USP monograph

Page 134

for valsartan products in the 2018 time period, so too they would have nothing from the monograph itself about identifying nitrosamines, correct?
A. Yes. I agree with that, Mr. Stanoch.
Q. Uh-huh. That does not mean, though, that the drug ultimately might not contain any nitrosamines, right?
A. Or that they might be controlled in another way.
Q. Correct. And it may be that even if a valsartan product was made according to the 2018 monograph, that the drug could still be adulterated under FDA regulations?
MS. LOCKARD: Objection. Vague. Speculation.
THE WITNESS: I'm struggling a little bit with what you said. Now, if you are citing the act, I think we would say it was not adulterated according to the provisions of the act that talk about a USP standard, but it could be adulterated under a private specification, which is allowed in the act in the citation I provided.
BY MR. STANOCH:
Q. Uh-huh.
A. Or it could be part of a GMP violation.

Page 135

Q. Let's take examples of some other drugs, Dr. Williams. Let's take an example of a drug that was made according to USP compendial standards. You with me so far?
A. I'm a little hesitant to talk about making a drug according to the standards because USP does not give process steps. So you might make a drug according to your process steps and then test it according to a USP monograph.
Q. Uh-huh. Well, that's a fair point, Doctor, that a manufacturer's individual process may have issues arise through it that are not covered by the monograph itself.
A. Yes, exactly.
Q. Right. And it would be incumbent on the manufacturer to understand its own individual process and to assess the potential for any impurities in the product even if the manufacturer is otherwise following the monograph, right?
A. I agree with the way you stated that. Thank you.
Q. Okay. And so let me go back to my example. I'll try to think -- I'll try to phrase it more accurately for you.
Let's take a drug that met all compendial

Page 136

requirements. Is that okay?
A. Okay.
Q. Is that an accurate articulation of a product, that it can meet compendial requirements?
A. It seems to me you are making a statement about a hypothetical, and I don't disagree with your hypothetical.
Q. Okay. So let's say there is a drug that meets all compendial requirements, but it contains anthrax. Is that drug adulterated?
MS. LOCKARD: Objection. Speculation.
MR. STANOCH: I can ask a hypothetical, Counsel.
Q. Go ahead, Dr. Williams.
MS. LOCKARD: Incomplete hypothetical. Objection.
THE WITNESS: You know, it's a hypothetical, and I would say, yes, it's got an unacceptable contaminant.
BY MR. STANOCH:
Q. Let's say a different, slightly different hypothetical. Say a drug met all compendial requirements but there was rat poison in it. Can it be adulterated?
MS. LOCKARD: Objection. Calls for

Page 137

speculation. Incomplete hypothetical.
THE WITNESS: Again, I would say it has a unacceptable contaminant.
BY MR. STANOCH:
Q. Even though the compendial requirements may not have a test for rat poison, correct?
A. Exactly.
Q. Uh-huh. And let's take another example. Let's say there is a drug that met all compendial requirements, but broken glass are in the capsules. Could it be adulterated?
MS. LOCKARD: Objection. Speculation. Incomplete hypothetical.
THE WITNESS: Well, it could be adulterated according to GMPs, but I think it could not be adulterated according to the compendial standard in the act.
I have got another good example, which is the tampering of the Tylenol many years ago where somebody put needles in the bottles. I don't know if you remember that, Mr. Stanoch. Do you recall that?
BY MR. STANOCH:
Q. No, I don't.
A. Well, FDA went to great trouble working

Page 138

with a highly responsible manufacturer to get that product off the shelves.
Q. And was that product considered adulterated because of the presence of needles in the bottles?
A. I think you could probably say that it was a GMP failure of some kind, but --
Q. Uh-huh.
A. At a certain point in time, FDA could take action, you know, as it deems appropriate for public health.
Q. Uh-huh. And in your example of the Tylenols with needles in the bottle, did a consumer who got a bottle with a needle in it before any FDA action, were they holding an adulterated product?
A. I can't remember the details. I think you are asking sort of a speculative question. I think you could say it was adulterated because of failure of GMPs.
Q. But you could --
A. You know, FDA has broad authority to remove adulterated products from the market. I can say that.
Q. Sure. I would agree with that. But you can have a product, in this example we're talking

Page 139

about, the consumer's holding a bottle of Tylenol with needles in it. That product they are holding is adulterated even prior to an FDA action against the manufacturer, is it not?
A. I think you could say that. I think people wouldn't quibble with that designation.
Q. Okay. You can say the same with sort of the other examples. For example, I mean, we talked about a drug made to compendial requirements that contained anthrax. That drug in a consumer's hand would be adulterated prior to the FDA taking official action against the manufacturer, correct?
MS. LOCKARD: Objection. Speculation. Incomplete hypothetical.
THE WITNESS: Yeah, I -- I'm sorry. I have lost track of your question. The hypothetical that the product has been willfully adulterated?
BY MR. STANOCH:
Q. The question simply was another example. I'll say it again. Assume you have a product that met all compendial requirements, except it also contained anthrax. You with me?
A. Yes. I think you are making general statements that are quite true, Mr. Stanoch, that the compendial standard really is designed to assess

Page 140

what is there according to tests, procedures, and acceptance criteria. It couldn't possibly assess all the possible negative things that might be there.
Q. Right. And in this example, assuming you have a product that met all compendial requirements except it also contained anthrax, the consumer holding that product is holding an adulterated product prior to any FDA action against that manufacturer, fair?
A. Yes. And as long as we're staying with these hypotheticals, I can say a valsartan monograph could have an impurity procedure for nitrosamines. Of course, it would take very specialized equipment, and it might have the limits set by FDA via the guidance. So there is nothing precluding that.
Q. So --
A. And I'm not exactly sure why it hasn't occurred, but maybe companies are figuring out a way to keep their manufacturing process such that the limits are met without testing.
Q. Okay. And you have not seen any USP monograph for valsartan that contains any impurity procedures for nitrosamines, right?
A. I have not.

Page 141

Q. Uh-huh.
MS. LOCKARD: We have been going about an hour since the last break, so whenever you get to a stopping point, I would like a break.
MR. STANOCH: Now is fine.
Doctor, would you like to take a break?
THE WITNESS: That would be nice, Mr. Stanoch. Thank you.
MR. STANOCH: Let's do it. Great.
THE VIDEOGRAPHER: Great. Then we are going off the record. The time is 10:49.
(Whereupon, a brief recess was taken.)
THE VIDEOGRAPHER: Okay. We are coming back on the record. The time on the video monitor is 11:07. Please begin.
BY MR. STANOCH:
Q. Welcome back, Dr. Williams.
A. Hi, Mr. Stanoch.
Q. Did you talk with anyone besides your counsel during the break?
A. No, I did not.
Q. Did you talk with your counsel during the break?
A. Yes, I did.
Q. And did you look at any documents during

Page 142

the break?
A. We sort of looked through the documents in the binder you provided, but we didn't review any. And we didn't get through all the documents. There were a few at the end we didn't look at, at all.
Q. You flipped through the binder of potential exhibits?
A. Yes.
MS. LOCKARD: Just very briefly.
MR. STANOCH: Counsel, I'm going to --
MS. LOCKARD: We didn't go through these documents.
MR. STANOCH: Counsel, and I didn't think I needed to state this, but I'll put on the record, I object to you flipping through the courtesy binder of potential exhibits we prepared at your request for the convenience of the witness.
Not all of them may be used. We want them not to be looked at, certainly to be destroyed without looking at them, the witness or counsel, especially when we're doing it as a courtesy to you and the witness, when we have asked for similar courtesies from your side, not you, Counsel, but other counsel on your side, we have been flat-out rejected when we have asked for hard copies.

Page 143

So it's very troubling to me that you are looking through all potential exhibits we provided, and I would ask that that not happen again, now or at a future deposition.
MS. LOCKARD: As the witness said, we did not discuss these documents. I'm trying to make sure I have copies of them in hand. We have one binder here that I'm having to walk over and look over Dr. Williams' shoulder, so --
MR. STANOCH: Every single document I marked from the binder, Counsel, is also put up on the screen for all counsel on the Zoom to see. So I would just ask that no one looks at the binder until the witness is directed to do it. Thank you.
MS. LOCKARD: Well, I would like to have hard copies in my hand because on some of these we don't even have the full document up on the screen, just showing pages.
MR. STANOCH: Well, first of all, that wasn't the request. It was for your witness.
Second of all, when we have asked for the same thing for our witness, let alone us, we have been flat-out refused by some on your side, not you. So going forward, we can talk about this, but again, for now I'm asking, do not look at the binder until

Page 144

an exhibit is marked. Thank you.
MS. LOCKARD: That's fine. You may have to give me a moment to find the document in hard copy if I need to. So --
BY MR. STANOCH:
Q. Did you look at any other documents, Doctor, during the break?
A. No, no other documents.
Q. Okay. Doctor, would you agree that if a manufacturer controls impurities and degradation products in accordance with only a pharmacopeial monograph, that is acceptable to regulators?
A. I think it can be, yes. If it is a good monograph, it can be sufficient to control the product in the marketplace.
Q. What if the individual monograph is inadequate to control an impurity?
A. If we're talking about the nitrosamine, I would say then there needs to be additional requirements that are private, agreed to with FDA.
Q. Uh-huh. Well, what agreements with FDA does any valsartan manufacturer have today, given that we looked at the valsartan monograph and there is nothing about nitrosamines in it?
A. Well, I can only speak to Teva, and the

Page 145

answer to that is clear, there are no Teva valsartan products in the U.S. marketplace. As we have already discussed, Teva immediately recalled them -- "immediately" can be a little debatable -- when the impurities were discovered.
Q. Uh-huh. Is it incumbent on the manufacturer that discovers an impurity to develop and validate appropriate analytical procedures, establish acceptance criteria, and communicate with USP?
A. There is no obligation for a manufacturer to work with USP at all. That's voluntary.
Q. Uh-huh.
A. I would say there is a requirement to do so with FDA if you come to the private specification.
Q. I'm going to mark the next exhibit. Stand by.
(Whereupon, Exhibit 8 was marked for identification.)
BY MR. STANOCH:
Q. I have marked Exhibit 8, Doctor, it's actually Tab 12 in your -- tell me when you're there, sir.
(Reporter clarification.)

Page 146

BY MR. STANOCH:
Q. Binder. Tell me when you are there.
A. Okay. I have been handed Tab 12, which looks like it's about 20 or 30 pages of a USP webcast. So I'm there, Mr. Stanoch.
Q. Very good. And this is a USP presentation entitled "Impurities in Drug Products and Drug Substances - A USP Approach," yes?
A. Yes.
Q. And you see the last update on the first page is March 2018, right?
A. Wait a minute. I'm trying to find March 2018. Where is that?
Q. Slide 1, lower left, light gray text.
A. Yes, it's very faint in my print, but yes, I can see it. Thank you, Mr. Stanoch.
Q. Not a problem. It's faint in mine too and in the original. That's why I was happy to draw your attention to it.
So this is prior to the valsartan recalls that began in the summer of 2018, right?
A. March 2018. Okay. I'm with you. Yes. Thank you. I agree.
Q. Good. Let's flip to Slide 36. So if you are looking at the little page numbers in the lower

Page 147

right, it would be the page that has Slides 35 and 36 on it.
A. 34. So I am looking at 35 and 36. Yes, I'm there.
Q. Okay. You see there is a Q and A on Slide 36, correct?
A. I do see that.
Q. And the question is: "If a manufacturer controls impurities and degradation products in accordance with only a pharmacopeial monograph, is that acceptable to the regulators?" Did I read that right?
A. Yes, you did.
Q. Then there is a three-bullet answer, correct?
A. Yes, I do see that.
Q. Okay. And it notes first the monographs are based on historic preparation, right?
A. Yes. I'm not exactly sure what that means, but you are reading it correctly.
Q. And then the next bullet notes that, "A particular manufacturer's manufacturing method for formulation components may lead to unexpected impurities, due to a different route of synthesis, different reagents, et cetera. Different processes

Page 148

may lead to different impurities."
Did I read that right?
A. Yes, you read that correctly.
Q. Do you agree with that statement?
A. I do agree with it.
Q. Then it also reads, "If an individual monograph is inadequate to control an impurity, the manufacturer is responsible for developing and validating appropriate analytical procedures, establishing acceptance criteria, and communicating with USP."
Did I read that right?
A. Yes, you did. And I agree with that statement.
Q. Okay. So what USP is advising in this slide is that it's -- the onus on the manufacturer to understand and evaluate its own process and any impurities that may arise in that process for a drug, correct?
A. Yes, I think you are stating it correctly.
Q. Uh-huh. If you can flip to the slide -- page 63. Let me know when you are there.
A. Okay. I'm on page 63, top of the page.
Q. Great. And it says, "Setting Acceptance Criteria for Impurities," right?

Page 149

A. Yes.
Q. And there is three bullets there?
A. Yes, I see that.
Q. Let me direct your attention to the third bullet. Are you there?
A. Yes.
Q. And read the first sentence for us.
A. "If a limit for a specified impurity does not exist in the USP, FDA recommends that you qualify the impurity by comparing it to the observed amounts of the impurity in the reference listed drug. Your acceptance criterion should be similar to the level observed in the" reference listed drug. "Alternatively, the acceptance criteria may be set based on a qualified level that is justified by scientific literature, metabolite data, or toxicity studies."
Q. Do you agree with that statement?
A. I do.
Q. Uh-huh. So the event that, say, a valsartan USP monograph did not contain a limit for a nitrosamine, the recommendation would be for the manufacturer to qualify the impurity, correct?
A. If the impurity existed in their product, I think you could make that claim.

Page 150

Q. Do you know if, prior to the summer of 2018, Teva ever made any effort to qualify any nitrosamine impurity in its valsartan products?
A. I think they did not. They did not suspect them, and their analytical tests in their private or public specification wouldn't have picked up a nitrosamine impurity.
Q. Uh-huh. Again, though, you don't know like what tests Teva in particular might have been employing for valsartan at the time, right?
A. Well, it seems to me we could assume they were following the USP monograph for valsartan --
Q. Uh-huh.
A. -- and valsartan drug product.
Q. Uh-huh. But you don't know how Novartis was able to detect NDMA in valsartan API whereas Teva did not?
MS. LOCKARD: Objection. Asked and answered.
THE WITNESS: Yeah, that is sort of a different set of questions. And Novartis would have been following the monograph, too, for valsartan and valsartan drug product if it existed.
BY MR. STANOCH:
Q. Well, that's sort of the point, Doctor,

Page 151

that Novartis, following the monograph that did not contain any mention of nitrosamines, nonetheless did a test that detected the nitrosamines, right?
MS. LOCKARD: Objection. Lacks foundation. Speculation. Outside the scope of his opinions.
THE WITNESS: Yeah, I have already stated, Mr. Stanoch, I have no understanding of what Novartis was doing.
BY MR. STANOCH:
Q. Would you agree, though, that Novartis performed some test that was not in the monograph that detected the nitrosamines, correct?
MS. LOCKARD: Objection. Speculation. Lacks foundation. Outside of his opinions in the class-certification report.
THE WITNESS: I think what I was trying to say is that when Novartis released its Diovan into the U.S. market, it would try to make sure it conformed to the USP valsartan and valsartan drug-product monographs. Those monographs, as I have already said, apply to brand and generic manufacturers.
Now, speaking hypothetically, any company, including Novartis, could do any kind of testing it

Page 152

wanted on another product for a myriad of reasons, but I just don't have any information about what Novartis was doing with the ZHP product.
BY MR. STANOCH:
Q. You look on the next page, on 65, sir. Tell me when you are there.
A. Yes. Top of the page?
Q. Yes. It reads, "USP General Chapters for Impurities: <476> & <1086>"?
A. Yes, I do see that.
Q. And these are examples of general chapters in the USP that would be part of so-called compendial requirements, correct?
A. Yes. I think we have alluded to this before in our prior discussion.
Q. Thank you. You can put that aside for now.
I'm going to mark the next exhibit. Stand by, sir.
(Whereupon, Exhibit 9 was marked for identification.)
BY MR. STANOCH:
Q. This will be Exhibit 9. It's Tab 13 in your binder, sir. Tell me when you are there.
A. Okay. I'm seeing it. It, again, is a USP

Page 153

document.
Q. Correct.
A. "Overview of" -- "General Chapters <476> and <1086>."
Q. Yes, sir. And the date on that document?
A. Another visual acuity test. I don't see --
Q. I see October 19th, 2017, right on the title page.
A. Oh, right, yeah. Right. Thank you.
Q. Is that right?
A. Yes, exactly, thank you.
Q. Oh, good. No problem. And have you seen this -- actually -- strike that.
Have you seen the last exhibit prior to today, sir?
A. No, I haven't, nor this one.
Q. Thank you. Okay. So let's flip to page 13, sir. Tell me when you are there.
A. And where will I see the page numbers?
Q. Oh, it's the lower right of the pages. The title is, "Manufacturers responsibilities in <1086> and <476>."
A. Okay. I'm there. I see it.
Q. Okay. In this slide in the USP

Page 154

presentation, sets forth what it says are "Manufacturer's Responsibilities in General Chapter <1086>" and "Manufacturer's Responsibilities in General Chapter <476>." Do you see that?
A. I do see that.
Q. And then why don't you read that first bullet that begins, "If a new impurity"?
A. "If a new impurity is detected above the appropriate identification threshold or when the level of a specified related compound increases as compared to its characteristic impurity profile, the manufacturer is responsible for evaluating the impact on the safety and efficacy of the drug substance or drug product."
Shall I continue?
Q. Do you agree with that -- no, why don't you -- just that bullet. Do you agree with that statement, sir?
A. Yes, I do.
Q. Okay. Why don't you read the second bullet.
A. "For marketed products, the manufacturers are responsible for controlling organic impurities in accordance with current regulatory standards."
Q. Do you agree with that statement, sir?

Page 155

A. I do.
Q. Could you read the next one under the subheading "Manufacturer's Responsibilities in General Chapter <476>"?
A. The first bullet?
Q. Yes, sir.
A. "If an individual monograph is inadequate to control does not include a procedure for qualifying an impurity or acceptance criterion for an observed impurity, the manufacturer is responsible for developing and validating appropriate analytical procedures and establishing appropriate acceptance criteria."
Q. Do you agree with that statement, sir?
A. Yes, it seems -- I can agree with it.
Q. Could you kindly read the next one, sir?
A. "Manufacturers shall validate or verify, as appropriate analytical procedures must demonstrate their suitability for detection and quantification of impurities in the drug substances and drug products."
Q. Thank you.
A. "Manufacturers shall develop" -- oh, I'm sorry. I went on.
Q. That's fine. Let's just stop there at

Page 156

that statement you just read. Do you agree with that statement, sir?
A. I do agree with it.
Q. And could you read the final bullet, sir?
A. Right. "Manufacturers shall develop acceptance criteria for impurities justified by appropriate safety considerations and consistent with current applicable regulatory guidances."
Q. Do you agree with that statement as well, sir?
A. I do.
Q. Okay. Thank you. Let's put that aside for now. Stand by for the next exhibit.
(Whereupon, Exhibit 10 was marked for identification.)
BY MR. STANOCH:
Q. I am marking Exhibit 10. Sir, that should be Tab 14 in your binder. Let me know when you are there.
A. Yes, I'm there.
Q. Okay. This is a slide deck from the FDA. You see that, sir?
A. I do. Dated October 2, 2020.
Q. Correct. And you see the two names of the presenters there, Dr. -- is it Keire and Dr. Lu?

Page 157

A. I do see those names.
Q. Did you work with them when you were at the FDA?
A. I don't recognize these names.
Q. Quite all right. And have you seen this slide presentation before, sir?
A. No, I haven't.
Q. Let's turn to page 3. Tell me when you are there.
A. Is this the one that states, "Pharmaceutical Quality"?
Q. Yes, sir.
A. Yes, I'm there.
Q. It states, "A quality product of any kind consistently meets the expectations of the user," correct?
A. Yes, I see that.
Q. And then flip to the next slide. You there?
A. Yes.
Q. Now it says, "A quality product of any kind consistently meets the expectations of the user. Drugs are no different," correct?
A. I see that.
Q. Do you agree with that characterization of

Page 158

pharmaceutical quality?
MS. LOCKARD: Objection. Outside the scope of his class-certification opinions. Vague.
THE WITNESS: I don't want to debate what the FDA is saying here, but I will say that users, sometimes including me, can be very uninformed about what the expectation for a product should be. But I don't want to debate it. You know, I certainly can agree with it generally.
BY MR. STANOCH:
Q. Understood. And would you agree, though, that users of a drug have no way of knowing if the drug contains nitrosamines absent the disclosure by the manufacturer or regulator?
MS. LOCKARD: Objection. Speculation. Vague.
THE WITNESS: Yes, some kind of disclosure. And I think you were more specific about what I was trying to say. It's very hard for a user to understand what the quality expectations of a medicine are.
BY MR. STANOCH:
Q. Uh-huh. And you can flip to the next page of the slide, sir.
A. "Patients expect safe and effective"?

Page 159

Q. Yes. Just read the sentence for me.
A. "Patients expect safe and effective medicines with every dose they take."
Q. As a general matter do you agree with that?
MS. LOCKARD: Objection. Calls for speculation. Vague.
THE WITNESS: Yeah, and it's very hard for me to know what patients really expect, but I certainly don't disagree generally with the statement.
BY MR. STANOCH:
Q. Uh-huh. And then let's flip to the next page, sir.
A. "Assuring every dose is safe"?
Q. Yeah. Why don't you just read that whole statement there on the slide?
A. "Pharmaceutical quality is assuring every dose is safe and effective, free of contamination and defects."
Q. Uh-huh. Do you generally agree with that statement?
A. Yeah, I don't see anything specifically objectionable.
Q. Uh-huh. And if you can flip to page 9,

Page 160

sir. You can tell me when you are there.
A. Oh, wait. Okay. Yes, I'm on 9.
Q. And here we see reference to the ICH M7 guidance again?
A. Yes, I do. Yes, exactly.
Q. And again, there is reference to the nitroso compounds being part of a cohort of concern, right?
A. Yes, I see that.
Q. I think we established earlier, but you can correct me if I'm wrong, that we agree that the ICH M7 includes nitroso compounds in the so-called cohort of concern, right?
MS. LOCKARD: Objection. Asked and answered. Outside the scope of his deposition.
THE WITNESS: Yes. And this is a very general statement, but I see nothing to disagree with.
BY MR. STANOCH:
Q. Go back to the slide we were looking at prior to this, the pharmaceutical quality slide.
A. "Pharmaceutical quality is assuring every dose"?
Q. Yes, sir.
A. I'm there, Mr. Stanoch.

Page 161

Q. Very good. Do you believe a valsartan drug that contained nitrosamines was safe and effective and free of contamination and defects?
MS. LOCKARD: Objection. Outside the scope of his expert opinion for class certification.
THE WITNESS: I'm sorry. Could you say the question again, Mr. Stanoch?
BY MR. STANOCH:
Q. Do you believe a valsartan drug that contained nitrosamines was safe and effective and free of contamination and defects?
MS. LOCKARD: Same objection. And vague.
THE WITNESS: Yeah. Speaking separate from my report, I think it's possible it could be free of contamination and defects, so I guess I'm answering yes to your question.
BY MR. STANOCH:
Q. And you opine that a, you know, recall is taken by companies to remove defective products in the market, correct?
A. Yes. I would say that's the general purpose of a recall.
Q. Uh-huh. Right. And so when Teva instituted its recalls for its valsartan products, it was removing defective drug product from the

Page 162

market, correct?
MS. LOCKARD: Objection. Outside the scope of his opinion. Also vague and speculation. Asking him to give legal opinion.
BY MR. STANOCH:
Q. I'm reading from your report, sir. There is no speculation.
A. Yeah, I would say Teva recalled its valsartan-containing drug products because of nitrosamine contamination.
Q. Right. And that contamination is what rendered them defective, making the voluntary recall action appropriate?
A. Well, but what --
MS. LOCKARD: Same objections.
THE WITNESS: The way I would say it, it was -- I'm hesitating on the word "contamination." The nitrosamines could be there within acceptable limits. When -- but working with FDA, Teva recalled even though the limits hadn't been set. I'm trying to be specific in terms of what my report says.
BY MR. STANOCH:
Q. Okay. And so let's slightly rephrase that, then, to see if we get on the same page. You write -- and you can look at Paragraph 69 of your

Page 163

report if you would like -- "A recall is a voluntary action taken by a company to remove a defective drug product from the market"; is that right?
A. All right. I'm going to my report.
Q. Of course.
A. Paragraph 69.
Yes, I'm reading from my report, and I see where you are reading, Mr. Stanoch.
Q. And you characterize elsewhere in your report that Teva's recalls of its valsartan products were voluntary, that's what you say, right?
A. Right, right.
Q. And the defect behind the Teva voluntary recalls of its valsartan products were the nitrosamine impurities; is that right?
MS. LOCKARD: Objection. Vague. Outside of the scope of his report.
THE WITNESS: Well, the way I would say it is FDA and Teva working together agreed that the levels of nitrosamine impurities were unacceptable. But I have also alluded in my report that it was unusual because neither FDA nor Teva at the time had a specific limit as to what was unacceptable.
But I don't think I'm debating you, Mr. Stanoch. Let me agree that the recall was

Page 164

because of a defective product.
BY MR. STANOCH:
Q. And is it your understanding that Teva recalled all of its valsartan-containing drug products in the summer of 2018?
A. No. No. I think there was -- the recalls in summer of 2018 were for the valsartan drug products using ZHP drug substance. And then, based on further information that came in over the fall, FDA recalled its valsartan drug products containing the Mylan product.
Q. Right. Were you aware that Teva initially instituted a hold on the marketing of all its valsartan finished-dose products when it heard from ZHP in late June 2018?
A. Yes. I think I am aware of that, and I think that's one of the documents -- there are two documents I cite in that regard.
Q. That is correct. And then shortly after its hold, Teva lifted its hold on valsartan finished-dose made with non-ZHP API, correct?
A. Yes, I think you are stating it correctly, because Teva had no reason to think that it had objectionable nitrosamine impurity levels.
Q. Right. And I'm going to put up a document

Page 165

just to help us with the timeline. Stand by, Doctor.
This will be Teva Exhibit 11. It should be Tab 24 in your binder, sir. Let me know when you are there.
(Whereupon, Exhibit 11 was marked for identification.)
THE WITNESS: Should I put away the FDA overview exhibit?
BY MR. STANOCH:
Q. Yes.
A. Yes, I see this lift of hold dated July 6, 2018.
Q. Very good. So this document appears to be a Teva memo dated July 6, 2018, about lifting hold status for certain valsartan products, correct?
A. Yes.
Q. And so sometime prior to this Teva, as we talked about, instituted a hold on all of its valsartan products, right?
A. Yes.
Q. Right. And then as of July 6, 2018, Teva, it appears, lifted its hold on valsartan finished-dose products that used non-ZHP valsartan API, correct?

Page 166

A. Yes, I agree.
Q. Uh-huh. And it looks like Teva had been using valsartan API from Jubilant as well, correct?
A. I would --
MS. LOCKARD: Objection. Speculation. Foundation.
BY MR. STANOCH:
Q. You can look at the document, Doctor.
A. I see the document. I wasn't aware that the Teva valsartan products used Jubilant drug substance.
Q. Oh, I see. You also see that Teva lifted the hold on valsartan products as of July 6, 2018, that contained API from Mylan, correct?
A. Yes, I do see that.
Q. Okay. I think you alluded to that a few questions ago, that you understood that Teva had used Mylan API for some valsartan products sold in the U.S., right?
A. Yes, particularly the -- I'm trying to think. These were the ones made in the Jerusalem facility.
Q. I would agree with that, sir, yes. I think we're on the same page.
Are you aware of any testing that Teva did

Page 167

of its own finished dose that -- just let me start over.
Are you aware of any testing that Teva did of its own finished dose that contained API from Mylan prior to its lifting the hold?
MS. LOCKARD: Objection. Vague.
THE WITNESS: I am not.
BY MR. STANOCH:
Q. Are you aware of whether Mylan tested valsartan API that it was selling to Teva prior to Teva's lifting its hold?
A. You know, I have a feeling that there may be some documentation in the materials considered, but I'm not aware of it and I didn't cite it in my report.
Q. Did Teva ever test its own valsartan finished dose that contained API from Mylan prior to Teva's recalling that product later in 2018?
MS. LOCKARD: Objection. Vague.
THE WITNESS: I just can't say. I didn't cite it in my report, so I don't know.
BY MR. STANOCH:
Q. Do you know when, if at all, Mylan tested valsartan API it was selling to Teva for nitrosamines after this July 6, 2018, hold memo?

Page 168

A. Well, my understanding of the sequence of events is Mylan was saying it couldn't be in their drug substance for valsartan, but Swissmedic did some testing, and that's when Teva became aware that there could be NDEA in the Mylan drug substance. And that went to Teva's recall in November of 2018.
Q. Uh-huh. Was it appropriate for Teva to lift its hold on products without testing it?
MS. LOCKARD: Objection. Outside the scope of his class-certification report.
THE WITNESS: Well, I don't know that they didn't test it, so I can't respond to that question.
BY MR. STANOCH:
Q. Uh-huh. Are you aware of whether tests had been developed after June 2018 to detect nitrosamines?
A. Well, the FDA was working on tests, and I think Teva was as well. And I think Teva's test didn't come along -- online until later, but I don't have those facts readily available now.
Q. Right. Right. Are you aware that, at the very least, the FDA announced in the summer of 2018 that it had found NDEA in a different manufacturer, Torrent's valsartan products?
A. I am actually not aware of that.

Page 169

Q. Uh-huh. And I can certainly pull up the notice, but the FDA said that Torrent products were included in the company's recall in August 23rd, 2018. Were you aware of that?
A. I'm sure I looked at it, but I'm not specifically aware of it until you mention it now, Mr. Stanoch.
Q. Uh-huh. You would agree, then, that if the FDA was testing and finding NDEA in a different manufacturer's product, there were testing methods available to determine NDEA by August 2018, correct?
MS. LOCKARD: Objection. Speculation. Vague. And outside the scope of his report.
THE WITNESS: Yeah, I just don't have information to answer the question.
BY MR. STANOCH:
Q. Uh-huh. Can you say one way or the other whether Teva ever tested any of its own product for NDEA prior to its November 2018 recalls?
A. I am sure that information exists, but I don't have it -- I didn't cite it in my report and I didn't comment, and so I can't answer.
Q. Okay. That's outside the scope of this report; is that fair?
A. But I would be guessing just because I

Page 170

don't have the information readily available.
Q. That's a little different. One is if you want the information, you can look at it in your report; but if you are not opining on it at this time, then you have no opinion at this time, sir. So which is it?
A. I think the way you said it second. I have no opinion at this time is a good way to state it.
Q. Very well, sir. We don't need to belabor it. Thank you.
Now, is it appropriate for a drug manufacturer to not test its drug for nitrosamines after being asked to do so by regulators?
MS. LOCKARD: Objection. That's a liability question, and it's outside the scope of his class-certification report. Also incomplete hypothetical, vague.
THE WITNESS: Do I answer?
MS. LOCKARD: If you are able to.
THE WITNESS: You know, I would generally say the answer to your question is no, it's not appropriate.
BY MR. STANOCH:
Q. Are you aware of whether Teva ever tested

Page 171

its valsartan product for any nitrosamines after receiving a request from any regulator to do so?
A. Well, I know they did test their nitrosamine -- I'm sorry, their valsartan-containing drug products at FDA's request, and they provided FDA with that information.
Q. And that was for NDMA, those tests, I think, right?
A. I agree, it was for NDMA, and I can't say whether it was for NDEA.
Q. Okay. If a finished-dose customer asked Teva, do your products contain NDEA, would it be appropriate for Teva to conduct that testing and see if NDEA is in the products?
MS. LOCKARD: Objection. Confusing. Vague.
THE WITNESS: Well, I would say if Teva had reason to believe that there was no NDEA in their valsartan products, Teva would refuse. I mean, it might be a very big deal to do that kind of testing.
BY MR. STANOCH:
Q. Uh-huh.
A. So I would say it's not appropriate.
Q. Uh-huh. And what information would you

Page 172

need to have reason to believe you may need to test your product for NDEA?
A. Well, I think in the particular example, Mylan was saying they had reason to believe that there was no possibility of NDEA being in their drug substance.
Q. Uh-huh.
A. And Teva could look at the other ingredients in the manufacturing process and conclude that there was no reason to test --
Q. Uh-huh.
A. -- and that it could be in the market. And I think that's what this memo speaks to.
Q. Okay. Did Teva, to your knowledge, in fact, look at the Mylan manufacturing process to determine whether or not NDEA could arise?
MS. LOCKARD: Objection. Vague. Outside the scope.
THE WITNESS: I can't say I can speak to that, Mr. Stanoch. My belief is they did. They were working with Mylan to get the needed information. But I don't have specific documents to support that view.
BY MR. STANOCH:
Q. Uh-huh. If we go back to the exhibit we

Page 173

were looking at a moment ago, the lift hold status memo; do you have that still, sir?
A. Yes, I'm looking at it. July 6, 2018?
Q. Uh-huh. Right. And it states that, "Mylan confirmed via e-mail to not have received any intermediates from Huahai." Do you see that?
A. I do see that.
Q. And further, so that -- strike that.
So that was one basis for Teva's lifting the hold of the Mylan API product, right?
A. Yes. And you can see in the last bullet on the thing where Teva's concluding possibility for NDMA impurity is negligible. I don't think the focus was on NDEA just yet.
Q. Uh-huh. Right. At the time Teva lifted its hold, it wasn't even discussing, at least in this memo, anything about NDEA, right?
A. Right. And I think that was the case for FDA. The concern about NDEA came later, after NDMA.
Q. Uh-huh. And what is your understanding of the route of how nitrosamines came to be in Mylan's valsartan API?
A. I have seen a description of it, and I think I have even seen statements from Mylan saying that the process was such that nitrosamines couldn't

Page 174

be formed. But beyond that, I don't have any specific information now.
Q. I mean, do you understand that it was an issue relating to the residual solvents that Mylan was using in the valsartan API manufacturing process?
A. Yes, I do understand that, and that relates to FDA's inspection of Lantech and a warning letter to Lantech about failure to look for the nitrosamine impurity.
Q. You are aware that Lantech was the vendor that was managing the solvent recovery process for Mylan when Mylan was making valsartan API for Teva, right?
A. Yes, I am aware of that.
Q. Uh-huh. And you understand that Lantech was faulted by the FDA for the manner in which it managed the solvent recovery process for Mylan, right?
A. Yes, I had that general understanding.
Q. And that was the root cause for the NDEA contamination of Mylan's valsartan API, right?
A. That's my understanding as well.
Q. Did Teva know that Mylan was using a solvent-recovery vendor in the manufacture of

Page 175

valsartan API?
A. I don't know that. I couldn't answer that question.
Q. All right. Sitting here today, can you recall anything you saw suggesting that Teva ever asked Mylan if Mylan was using a vendor for the solvent recovery process in the manufacture of valsartan API?
A. I can't answer that. I don't have that information.
Q. Uh-huh. Did Teva know that Mylan was using recycled solvents at all in the manufacture of valsartan API?
A. I can't say what Teva knew or didn't know.
Q. Sitting here today, can you tell me anything you saw suggesting, even, that Teva knew that Mylan was using recycled solvents in the manufacture of valsartan API?
A. I think there is information about it, but I don't have it and I can't comment.
Q. Uh-huh. Right. You can't elaborate any more on that, can you?
A. No.
Q. Right. Shouldn't Teva, as the finished-dose manufacturer, understand whether or

Page 176

not its API supplier was using recycled solvents in the valsartan API manufacturing process?
MS. LOCKARD: Objection. Lacks foundation. Outside the scope of his report.
THE WITNESS: You know, well, one of the ways I might answer that question is that the DMF system might preclude Teva from knowing because the processes of the DMF may be secret between Mylan and Teva.
BY MR. STANOCH:
Q. Well, do you see anything suggesting that Teva ever asked Mylan about whether it was using recycled solvents?
A. I don't recall seeing any information to that point.
Q. Do you recall looking at anything suggesting that Teva ever asked to see Mylan's DMF for valsartan API?
MS. LOCKARD: Objection. Asked and answered. It's outside the scope.
THE WITNESS: No, it wasn't a focus of my report, and I don't recall seeing it.
BY MR. STANOCH:
Q. Do you agree that the "Residual Solvents" chapter of the USP would be part of the chapters and

Page 177

notices which manufacturers should take into account when they are manufacturing their own finished-dose valsartan?
MS. LOCKARD: Objection. Vague.
THE WITNESS: I think "Residual Solvents" is an ICH document that is important to manufacturers as a recommendation, so I think I would answer that yes.
BY MR. STANOCH:
Q. Uh-huh. Do you know whether Teva adhered to the USP "Residual Solvents" Chapter 467 in assessing the valsartan API it purchased from Mylan?
A. I think my understanding would be that in the certificate of analysis for valsartan, there may be a test for residual solvents. And we could certainly look at that.
Q. Well, you looked at a number of certificates, I believe, listed in your materials considered, right?
A. No. That doesn't mean I looked at them. They are listed in my materials considered, but they weren't important to my report and I didn't cite them.
Q. Fair enough. Can you say sitting here today whether you saw any mention of the use of

Page 178

recycled solvents by Mylan in the manufacture of valsartan API?
A. No, I didn't see anything about recycled solvents.
Q. And a moment ago you were talking about the potential confidentiality of DMFs. Do you remember that?
A. I do.
Q. Is the mere existence of a third-party vendor secret?
MS. LOCKARD: Objection. Foundation. Speculation.
THE WITNESS: I don't quite understand. Secret from whom?
BY MR. STANOCH:
Q. Does the fact that Mylan was using a third-party vendor, Lantech, to manage the solvent recovery process for valsartan API -- strike that.
You were suggesting, were you not, that some of Mylan's DMF might have been confidential and not shareable with Teva, right?
A. Right, right.
Q. Right. So is it your position, sir, that the mere fact that Mylan was using a third-party vendor at all for the solvent recovery process was

Page 179

something that would be confidential and not shareable with Teva?
A. Well, it could be. I just don't know what Mylan wanted to keep confidential in the DMF.
Q. Uh-huh. And if -- oh.
A. And again, remember, typically what you see in the DMF for the purchaser, in this case, Teva, is the certificate of analysis, the specification for the drug substance.
Q. And again, those certificates and analysis, to the extent you recall sitting here today, made no mention of the use of recycled solvents?
A. It may have a specification for residual solvents. We would have to look at one to see. But I don't think that necessarily would tell anything about whether the solvents were recycled or not.
Q. Uh-huh. And one way Teva could have had additional information about Lantech would be if it had a quality agreement in place with Mylan, correct?
MS. LOCKARD: Objection. Speculation.
THE WITNESS: You know, quality agreements may relate to contract manufacturers, but for both ZHP and Mylan, these are not contract manufacturers.

Page 180

These are sellers of a drug substance that Teva purchased.
BY MR. STANOCH:
Q. Uh-huh. So it's your position that -- oh, strike that.
Would it surprise you to know that Mylan was contracting with a third-party vendor in India who had never been inspected by the FDA?
A. No, it wouldn't surprise me.
Q. And do you think Teva would have any issue if it learned that Mylan was contracting with a third-party vendor in India who had never been inspected by the FDA?
MS. LOCKARD: Objection --
MR. STOY: Frank Stoy for Mylan. I am just going to object to the form of the question.
(Reporter clarification.)
MR. STOY: Yes, I just stated an objection to the form of the question. Thank you.
MS. LOCKARD: I objected as well as vague. And calls for speculation.
THE WITNESS: But I feel like I'm losing Mr. Stanoch.
BY MR. STANOCH:
Q. Can you hear me, sir?

Page 181

A. Yeah, now I can hear you clearly.
Q. I will repeat the --
A. Can you repeat --
Q. I would love to because of the interference -- I don't mean that pejoratively -- from defense counsel.
Sir, do you think Teva would have an issue if it learned that Mylan was using a third-party vendor in India who had never been inspected by the FDA to manage the solvent recovery process?
MS. LOCKARD: Same objection.
THE WITNESS: I can't really speculate what Teva would think about it. It doesn't seem to me a big issue whether there is or is not an FDA inspection.
BY MR. STANOCH:
Q. It's not a big issue if Teva was buying valsartan API from Mylan where Mylan was using a third-party vendor not disclosed to Teva who had never been inspected by the FDA; is that your testimony?
A. I'm not really an expert on solvent recovery processes, but my understanding is that many companies use them. It's not unusual. And to me it might be part of the DMF that Mylan would want

Page 182

to keep confidential.
And then the issue of an FDA inspection is -- to tell you the truth, Mr. Stanoch, when I saw that FDA had inspected Lantech, this was the first time I had ever heard of FDA inspecting a solvent-recovery manufacturer.
Q. Uh-huh. And that happened after news of the nitrosamines broke in 2018, though, right?
A. Yes, that's when the inspection occurred for Lantech.
Q. Right. And Teva never inspected Lantech prior to 2018, did it?
A. I don't know that.
Q. Right. And did you see anything in any of the documents you reviewed suggesting that Teva ever inspected Lantech prior to 2018?
A. No, I didn't see anything like that.
Q. And you never saw anything even suggesting Teva knew who Lantech was prior to 2018, correct?
A. I never saw anything to that point.
Q. Would it surprise you to know that Mylan was also using Lantech to do second-crop harvesting of valsartan API?
MS. LOCKARD: Objection. Foundation. Speculation. Outside the scope of his report.

Page 183

THE WITNESS: I don't understand the question and I have no information to answer it.
BY MR. STANOCH:
Q. Uh-huh. Teva could not make its assessment about the recycled-solvent process without knowing anything about it, correct?
MS. LOCKARD: Objection. Vague.
THE WITNESS: That seems like a generally true statement, so I can agree.
BY MR. STANOCH:
Q. Uh-huh. And absent a contractual arrangement that would obligate Mylan to disclose that information, Mylan didn't have to disclose it to Teva; is that your statement?
A. No, I'm not making that statement.
Q. Uh-huh. If there was a contract between Mylan and Teva that governed disclosure of the processes and entities involved in the valsartan API manufacturing process, Teva could have learned about Lantech prior to all the recalls in 2018, right?
MS. LOCKARD: Objection. Speculation. Foundation. Outside the scope of his class-certification opinions.
THE WITNESS: Yeah, I would have to speculate on that. I just have no information to

Page 184

support an answer.
BY MR. STANOCH:
Q. Okay. Wouldn't a contract between Mylan and Teva allow those two firms to exchange confidential information?
MS. LOCKARD: Objection. Speculation. Outside the scope.
THE WITNESS: I could imagine a contract that would support that kind of exchange of information.
BY MR. STANOCH:
Q. Right.
A. But it can occur without a contract.
Q. It certainly could, but that exchange did not occur here between Teva and Mylan about the recycled solvents and Lantech, did it?
A. I just have no information to that point, but if that's what you say, I certainly wouldn't debate you.
Q. And you would agree, though, that Teva could have contractually required Mylan to disclose information about the solvent recovery process, correct?
MS. LOCKARD: Objection. Speculation. Outside the scope.

Page 185

THE WITNESS: Yeah, again, everything you are asking me, I would be required to speculate because I just don't have the information.
BY MR. STANOCH:
Q. Do you know whether Teva ever performed a residual solvent analysis with respect to Mylan valsartan API?
A. I do not.
Q. Do you know whether Mylan itself ever conducted a residual solvent analysis for the valsartan API it made?
A. I do not know that.
Q. Uh-huh. Did Teva ever ask to audit Lantech?
A. Not that I'm aware of.
Q. Right. Teva didn't even know who Lantech was, right?
A. I don't know that.
Q. Do you have any information suggesting that Teva knew about Lantech and its role in the Mylan valsartan API manufacturing process prior to the recalls?
MS. LOCKARD: Objection. Speculation. Foundation. Outside the scope.
THE WITNESS: I just don't know, and it

Page 186

wasn't pertinent to my report.
BY MR. STANOCH:
Q. Uh-huh. Are you aware of any evidence that Teva ever reviewed ZHP's route of synthesis for valsartan API prior to the 2018 recalls?
MS. LOCKARD: Outside the scope. Objection.
THE WITNESS: Well, I think if we look at the Watson CBE-30s -- Watson, of course, is a predecessor company to Teva -- there was information about the route of synthesis and the synthesis change.
BY MR. STANOCH:
Q. You are talking about the ZHP process change, correct?
A. Yes.
Q. Right. And regarding that, ZHP was changing its manufacturing process for valsartan API that it was selling to, at the time, Actavis, correct?
A. I would say Watson, but they were all predecessor companies to Teva.
Q. That's fine. We can agree that Watson was a predecessor to Actavis and then Actavis was a predecessor to current Teva, right?

Page 187

A. Yes, that sounds right.
Q. Great. So we can use -- we can understand that as we go through. So ZHP changed it manufacturing process for the valsartan API it was selling to Watson, right?
A. Yes, that's correct.
Q. And ZHP characterized that as a minor to moderate change, correct?
A. I would have to see the letters from Watson to FDA, but I think you are correct.
Q. And a minor to moderate process change does not require preapproval from the FDA, does it?
A. Well, I couldn't agree with that, because Watson was asking for FDA approval, but they submitted it as a CBE-30.
Q. Right. And a CBE-30, Change Being Effected, does not technically require preapproval by the FDA, correct?
A. The way I would say it is FDA will always come in and review it, but the change can be implemented if FDA doesn't respond within 30 days.
Q. Right. A major process change requires a different level of review by the FDA, correct?
A. That would be called the postapproval supplement.

Page 188

Q. So the fact that Watson characterized the ZHP process change as minor to moderate meant that it could implement its change immediately if it wanted, correct?
A. Well, I would say the letter was the CBE-30, so they would wait to hear from FDA and then they could implement after 30 days.
Q. Uh-huh. And in that context of that submission, did Watson, to your knowledge, review ZHP's entire DMF?
A. As far as I know, they did not.
Q. All right. Did Watson, Actavis, or Teva, to your knowledge, ever ask ZHP for a copy of ZHP's DMF for valsartan API?
A. As far as I know, they did not.
Q. Nothing stopped any of them from requesting that, correct?
A. Well, I think it would be counter to the way a DMF works, that it's a separate filing to the agency. So I would say Teva would not ask for it.
Q. Well, that wasn't quite my question, sir. The question was that nothing stopped Teva or its predecessor entities from asking ZHP for a copy of the DMF for valsartan API, correct?
A. I think you are correct. I mean, the two

Page 189

companies could agree to completely share the contents of the DMF.
Q. Right.
A. But typically a DMF is not shared with the purchaser, such as Teva.
Q. Uh-huh. And the DMF was not shared in this instance, as far as you know, with Teva or its predecessor entities?
MS. LOCKARD: Objection. Asked and answered.
THE WITNESS: I have to say I just don't know. If I had to guess, I would say not.
BY MR. STANOCH:
Q. Uh-huh. To your knowledge, did Teva ever ask ZHP to confirm that ZHP's valsartan API did not contain any genotoxic substances?
A. As far as I know, it was not an issue or a basis for communication until the summer of 2018.
Q. Nothing's prevented Teva from ever asking ZHP to confirm that ZHP's valsartan API did not contain any genotoxic substances, correct?
A. Are you saying nothing prevented them?
Q. Yes. I'll restate it. Nothing prevented Teva from ever asking ZHP to confirm that ZHP's valsartan API did not contain any genotoxic

Page 190

substances, correct?
A. Well, if it was expected, I suppose Teva could certainly have asked, but it was unexpected.
Q. Well, it was unexpected because ZHP said so; isn't that right?
MS. LOCKARD: Objection to form.
THE WITNESS: No, the reason I say it was unexpected, because FDA said so.
BY MR. STANOCH:
Q. Well, FDA said it's unexpected because that's how ZHP characterized it originally when it was forced to break all this news in June 2018; isn't that right?
MS. LOCKARD: Objection to form.
MS. HILL: Objection. Argument.
THE WITNESS: I just don't know that, Mr. Stanoch. If you know that, it's news to me.
BY MR. STANOCH:
Q. Uh-huh. Uh-huh. Do you have any information as to where FDA may have gotten the term "unexpected" as to the nitrosamines found in valsartan products?
A. I don't.
Q. And would it surprise you if it came originally from ZHP?

Page 191

MS. LOCKARD: Objection. Speculation. Foundation.
THE WITNESS: Yeah, I just can't answer. I don't know where it came from.
BY MR. STANOCH:
Q. Uh-huh. If ZHP told the world this nitrosamine impurity was unexpected, but it had information suggesting it knew a year earlier, would that be important?
MS. LOCKARD: Objection to form.
THE WITNESS: I just have to speculate. I don't know when ZHP had its information. It seemed to me it was closer to the summer of 2018 time frame.
BY MR. STANOCH:
Q. Uh-huh. Did you evaluate whether ZHP had any information suggesting there may be nitrosamines in its valsartan API prior to June 2018?
A. I did not see any information to that point.
Q. Was that even part of your analysis for purposes of your class-certification report?
A. No.
Q. Uh-huh. In the context of your consulting work, sir, would you advise a company to purchase

Page 192

API from ZHP?
A. I think now they have resolved their issues with FDA, as I understand it, that arose and were summarized in the warning letter, and everything is fine between FDA and the company.
Q. Uh-huh. So you would?
A. Yes.
Q. Uh-huh. How about before 2018?
MS. LOCKARD: Objection. Vague.
THE WITNESS: Well, I would say yes. My understanding is they had good FDA inspections, and many companies get warning letters where things can be resolved, and that's what happened for ZHP.
BY MR. STANOCH:
Q. Uh-huh. And it's important, then, to know if your API supplier is receiving any adverse inspections from the FDA, correct?
A. That's a separate topic. And -- is that a question? I'm sorry.
Q. It's important to know if your API supplier is receiving any adverse inspection findings from the FDA, correct?
A. I think it could be important, yes.
Q. Okay. Yes. And a reasonable pharmaceutical manufacturer would want to know if

Page 193

its API supplier is receiving adverse inspections and findings from the FDA, correct?
MS. LOCKARD: Objection. Outside the scope. That's clearly a liability question.
THE WITNESS: And I -- you know, there are so many variables underlying your question. I mean, FDA may inspect and make a few observations that are quickly resolved. I'm not sure that needs to be communicated to buyers.
BY MR. STANOCH:
Q. Uh-huh. If a manufacturer of finished-dose product learns about an FDA inspection and requests information about it from its API supplier, would it be your expectation that the API supplier would provide the information?
MS. LOCKARD: Objection. Speculation. Foundation. Incomplete hypothetical.
THE WITNESS: Yes, and I just don't have any basis to have an answer to that question.
BY MR. STANOCH:
Q. Well, you consult pharmaceutical manufacturers, don't you, sir?
A. I would say now I am doing primarily litigation, and I have never consulted on the type of questions you are raising now.

Page 194

Q. Right, uh-huh. Have you ever advised a company that it's prudent for them to have all available information about regulatory inspections of their API supplier?
A. I have not.
Q. Uh-huh. Are there ways for pharmaceutical manufacturers to independently check on whether their API suppliers have had adverse regulatory findings?
A. Well, certainly a warning letter is public, so that could come to light independent of a drug-substance manufacturer.
Q. Uh-huh. Are you aware of any processes Teva had in place prior to June 2018 to monitor whether its API suppliers were receiving adverse findings from regulators?
A. I am not.
Q. Uh-huh. And back to ZHP and Teva. To your knowledge, Teva never asked ZHP to confirm that ZHP's valsartan API did not contain any genotoxic substances, correct?
MS. LOCKARD: Objection. Asked and answered.
THE WITNESS: Yes, I am not aware of any communication like that.

Page 195

BY MR. STANOCH:
Q. Uh-huh. Wouldn't it have been prudent for Teva to request such a statement from ZHP regarding the valsartan API?
MS. LOCKARD: Objection. Outside the scope of his report. It's liability opinion.
You are just -- I'm sorry, Mr. Stanoch, but you have just completely disregarded any sort of line, bright or not, between liability opinion and his class-certification opinion. I'm honestly at a loss as to whether we need to suspend and call a judge or meet and confer on this.
But, I mean, I hate to just keep objecting to every question, but every question is, you know, what would a prudent manufacturer do? What would be reasonable? You know, what should they do? Would it be appropriate? These are all liability opinions.
MR. STANOCH: Are you done, Counsel?
MS. LOCKARD: No, because I'm having a problem here.
MR. STANOCH: Are you done, Counsel?
MS. LOCKARD: No. Do you want to go off the record or you want to discuss it on the record? What is your response?

Page 196

MR. STANOCH: Counsel, I'm not debating you now on the record. I'm going to keep asking my questions. You are lodging your objections. I'm asking questions on the facts on which he is opining about. It's within the scope of his report.
He says a number of factual --
MS. LOCKARD: I just want to --
MR. STANOCH: Excuse me. He makes a number of statements about facts. I'm entitled to probe the facts as they relate to the opinions in this report.
MS. LOCKARD: You are not asking about facts, though. You are asking about his opinion as to whether something is reasonable, prudent, appropriate, and those are the questions that I'm objecting to. Now, I understand --
MR. STANOCH: You have stated your objections.
MS. LOCKARD: -- you are going to keep asking, but we're going to move to strike all this testimony and you are not going to be able to come back and ask him or anyone else these questions.
MR. STANOCH: Well, I disagree with that. I'm asking him questions relating to the facts and the opinions in this report. And we will keep

Page 197

going.
MS. LOCKARD: Well, this will be taken up with Judge Vanaskie, so --
MR. STANOCH: I don't appreciate the threat, Counsel.
MS. LOCKARD: It is not a threat -- a statement. But go ahead.
MR. STANOCH: For the record, Counsel, I'll state that in his own report, Dr. Williams opines on reasonableness a number of times in terms of methods, in terms of what one would do, in terms of risk assessments, et cetera, so it's in the report. We can look at it later.
Q. So, Doctor --
MS. LOCKARD: I disagree with your assessment.
(Reporter clarification.)
MS. LOCKARD: I said I disagree with the assessment, but go ahead.
BY MR. STANOCH:
Q. Uh-huh. Dr. Williams, you state in Paragraph 84 of your report that there is no issue with the FDA inspection of ZHP in 2017 because an EIR was provided; is that right?
A. Wait a minute, if I could get to where you

Page 198

are now. Which paragraph?
Q. 84.
A. And what page? Yeah.
Q. I don't have a printed copy of the report you produced this morning, so I can't tell you the exact page, sir. Sorry. It's Paragraph 84.
A. Page 28. Yes. And, of course, others will comment on ZHP's inspectional history, but this is an example of an inspection that ZHP got in 2017, an FDA 483 with a small number of observations, and as FDA does, they provided an EIR, indicating that the inspection was closed.
Q. Are you suggesting here that because the FDA did not continue the inspection, there were no problems with ZHP's valsartan API?
A. Well, that's a difficult question to give a conjecture about. What I would say is I can't say more than what the facts state, that ZHP responded to the observations, FDA found them satisfactory and issued an EIR.
Q. Was Teva ever made aware of the FDA inspection of ZHP's facility in 2017? Did it learn of that in the year 2017?
A. I don't know that.
Q. Right. Do you know when, if at all, Teva

Page 199

learned that FDA inspected ZHP's API facility in 2017?
A. I'm not aware of what FDA knew about ZHP inspectional history. Of course they knew about the warning letter because that was public.
Q. Well, the warning letter was from 2018, after the recalls, right?
A. Yes.
Q. Right. So I'm asking -- a different question is: What is your understanding of when Teva knew about the FDA inspection of ZHP that occurred in 2017?
A. I have no information about that.
Q. Right. So you don't know one way or the other when Teva might have learned that the FDA inspected ZHP's API facility in 2017?
A. Yes, I don't know that.
Q. Do you know when if at all ZHP revealed the observations from the 2017 FDA inspection to Teva?
A. I don't know that they revealed it to Teva.
Q. Was Teva ever relying on the FDA to determine the acceptability of ZHP's valsartan API?
A. Well, I think Teva would be aware that FDA

Page 200

was reviewing the DMF and was certainly likely to imagine that FDA would inspect ZHP, so it would be hard to imagine that Teva didn't have some understanding of those possibilities. But in terms of the discrete facts of those possibilities, I have no information.
Q. Uh-huh. Is there only a potential cGMP problem with an API supplier if the FDA catches it first?
A. No. I don't think that is a fair statement. I would say the essence of GMPs is the manufacturer is supposed to create their own approach to GMPs that then is suitable for an FDA inspection, but the FDA inspection may occur infrequently.
Q. Uh-huh. Right. It's incumbent on a manufacturer sourcing API to conduct its own due diligence of the API manufacturer, correct?
A. Are you talking about the purchaser?
Q. Yes. It's incumbent on the finished-dose manufacturer purchasing API to conduct its own due diligence of the API supplier, correct?
A. I think that's a reasonable statement, yes.
Q. Uh-huh. And further down in your report,

Page 201

beginning Section F, do you see this? It's "FDA Inspections of Teva Drug Product Manufacturing Facilities"; do you see that, sir?
A. I do.
Q. Okay. And here you talk about FDA inspections of Teva's own finished-dose facilities that had been manufacturing valsartan prior to the recalls; is that fair?
A. Yes, FDA inspections.
Q. Right. And are you suggesting that just because the FDA didn't find a problem relating to valsartan, that there was no issue with the valsartan API that the Malta and Jerusalem facilities were sourcing from ZHP and Mylan?
A. I don't know that. I couldn't comment.
Q. And are you suggesting here that because the FDA did not find any adulteration during the inspections you list in your report here, that Teva's product could not be adulterated with nitrosamines during these same time periods?
A. I'm saying that Teva in my report had recalled all its valsartan products from the market before FDA made any determinations related to adulteration.
Q. Well, Teva's products had API with

Page 202

nitrosamines in it prior to the recalls, right?
A. Yes, I think that was the basis for the recall.
Q. Right. So are you telling me that a valsartan product made by Teva the day before the recalls with nitrosamines is not adulterated, but then once the recall is issued the next day, now that product is adulterated?
A. No, I'm saying the adulteration label, if somebody wanted to say, when did it occur, it occurred with the warning letters that went to ZHP and Mylan, and it also occurred after FDA set limits for the nitrosamine impurities in December 2018. But before that, Teva had recalled all product from the U.S. market.
Q. Uh-huh.
A. Both made in Jerusalem and Malta.
Q. Uh-huh. Are you saying that valsartan sold by Teva prior to the FDA's issuance of warning letters to ZHP and Mylan could not be considered adulterated?
A. Yes.
Q. So a Teva valsartan product on a certain day that had nitrosamines in it is not adulterated until the FDA issues a warning letter to ZHP or

Page 203

Mylan, and then once that happens, then it's adulterated?
A. That's when a formal regulatory definition of adulteration could be stated to have occurred. And it could also have been stated to have occurred when FDA set limits for nitrosamine in December of 2018.
Q. So going back to our examples we had talked about before a couple breaks, if there is a product that is containing anthrax, it's not adulterated until the FDA issues a Form 483?
A. No, no, no. I would say a 483 is not a FDA determination of adulteration. A regulatory determination of adulteration by FDA is a very serious matter and, you know, it's carefully considered by FDA, and I am suggesting that it could have been determined to have occurred on those three points that I just stated.
But Teva had recalled all of its product before FDA made any kind of statement that could be deemed an interpretation of adulteration.
Q. So it sounds like the only three points that you say adulteration could be found is when, number one, FDA issued a warning letter to ZHP, right?

Page 204

A. Yes, yes, go ahead.
Q. Number two would be when FDA issued a warning letter to Mylan, right? Right?
A. Yes, uh-huh.
Q. Number three would be when FDA set interim limits, which you say occurred in December of 2018, correct?
A. Yes, I think that's -- I'm looking at my report to see if those opinions are clearly stated. Let me check. But that corresponds to my opinion.
Q. So let's say the FDA never set interim limits and let's say the FDA never issued warning letters to ZHP or Mylan. In that case, Teva's finished-dose valsartan could never be considered adulterated, according to you?
A. Yes, I think the issue of adulteration arose and was determined, to the extent it was determined at all, after Teva had recalled all product from the market.
Q. So then the answer is that Teva's valsartan products would never be considered adulterated in a world where the FDA did not issue warning letters to ZHP and Mylan and the FDA set no interim limits?
A. Yeah, I don't think FDA -- yeah, if we

Page 205

say, was the Mylan product adulterated, I would say it couldn't -- FDA had not made a decision in that regard at least until those three prongs, if you will, had been met.
Q. Say a warning letter finds a product adulterated on January 1, 2022. Does that mean that on December 31, 2021, that same product was not adulterated?
A. Yeah, I think the issue of adulteration is -- and I'm looking at page 8 in my opinion, under B, and my opinion is clear. "My opinion that Teva's valsartan products were, at all times prior to Teva's voluntary recalls, AB-rated to their branded counterparts and were not adulterated or misbranded." That's what I'm saying.
Now, if somebody wants to raise an issue of when adulteration occurred, I would say it was when the warning letters went to ZHP and Mylan or when FDA set limits on the nitrosamine impurities in December 2018. I think that's a very clear conclusion on my report.
Q. Well, how does the FDA take action for adulterated product, then, for product that had already been sold if nothing is adulterated until they issue a warning letter?

Page 206

A. FDA can ask for recalls of products that are objectionable for various reasons. You mentioned examples yourself. But it doesn't mean that FDA is making an adulteration charge. That's a separate issue.
Q. So according to you, adulteration can only exist if the FDA issues a warning letter?
A. I would say an adulteration charge is a regulatory determination by FDA that is very carefully considered. Even a warning letter doesn't necessarily mean, you know, an adulteration charge. It's really a signal to a company that they need to focus a little bit more on improving their GMPs.
All I'm saying is that Teva products were not adulterated at the time of the recall, so Teva never had adulterated product in the U.S. market.
Q. Because you are saying the warning letters were not issued to ZHP or Mylan until after Teva's recalls?
A. Yes. If somebody wants to make an adulteration claim here, it seems to me it would occur then, or when FDA set limits and a product was above those limits. The FDA -- oh.
Q. So all the --
A. FDA could have set limits that would have

Page 207

let the Teva product be okay. It was just an uncertainty there. But because FDA thought the limits were unacceptably high, without a limit being set, Teva and FDA agreed that these products should come off the market, first ZHP-containing product and then the Mylan product.
Q. Uh-huh.
A. And then Teva decided not to reenter the market at all.
So Teva never had an adulterated product for any of its four valsartan-containing products in the U.S. market.
Q. Uh-huh. So from 2012 on, assume all of Teva's products had nitrosamines in it leading up to the recall. You are saying all of that product cannot be considered adulterated?
A. It was not adulterated --
Q. Uh-huh.
A. -- according to an FDA regulatory determination.
Q. Uh-huh. The FDA found that the API that Teva was using that entire time was adulterated, though, correct?
A. When do you say that occurred?
Q. Well, you tell me. It's in the 483s that

Page 208

you cite in your report, sir.
A. Is it? I don't recall FDA making an adulteration claim in the 483s. Can you show me that?
Q. In the warning letters, I apologize. In the warning letters the FDA said that Mylan and ZHP's API was adulterated, correct?
A. Yes. I mean, you are reiterating my claim. That's a point at which FDA could be said to have determined a charge of adulteration.
Q. Uh-huh. So --
A. And that is a very carefully considered charge.
Q. All right. So if I am selling a product starting today, and it contains rat poison, I can keep selling that and keep selling it until the FDA issues me a warning letter, correct?
A. No. I think your hypothetical, it needs to be refined for this particular case. There is an impurity, an impurity that we have already talked about is undesirable. It's part of that cohort of concern.
But it can have a limit set on it such that the product is safe and effective and of good quality. FDA did not do that until December 2018.

Page 209

But FDA still had the concern that the levels were too high, so they worked with Teva to recall all product.
This is separate from a determination of adulteration. The only time I have ever seen adulteration raised in this matter is when FDA sent those warning letters, as you say, to ZHP and Mylan.
Q. If not adulterated, what would you call all of Teva's products prior to the FDA's issuance of warning letters to ZHP and Mylan?
A. I would call them AB-rated and of good value to the consumer.
Q. Even if they contained genotoxic impurities above any limit that was ever set to the present?
A. Well, you are getting to the core issue in this matter.
First of all, my claim is, and I state it in my report, they were AB-rated. They were pharmaceutically equivalent. They were bioequivalent. They were not misbranded. They had the appropriate labeling relative to the Novartis reference listed drug.
Now, if you have an impurity that comes to light, it's a very low-level impurity, it was

Page 210

unexpected, there are not analytical procedures to adequately measure it, it all of a sudden comes to life, does that make the product worthless? No. It makes the product really fine until FDA and the companies sort through what the appropriate limits should be.

Teva didn't do anything wrong. They were making good product at their Malta and Jerusalem facilities. And then FDA comes up with a limit. So then you can say, okay, well, products in the marketplace shouldn't have nitrosamine impurities above that limit. And before all that occurred, Teva had removed all product from the market.

Q. Uh-huh. Are you familiar with the FDA's actions against Ranbaxy concerning generic Lipitor?

MS. LOCKARD: Outside the scope.

THE WITNESS: You know, I could probably be reminded of it, and please do if you think it would be helpful -- if you think it would be helpful, please remind me of that.

BY MR. STANOCH:

Q. Sure. I'll mark Exhibit 12.

(Whereupon, Exhibit 12 was marked for identification.)

Page 211

BY MR. STANOCH:

Q. Unfortunately, I don't think it's in your binder, but it's relatively short. Let me know when you can see it.

A. I think it's coming to me; is that right?

MS. LOCKARD: It's not in the binder, so it's only on video screen.

THE WITNESS: And I don't see it on the video screen yet.

(Whereupon, a brief discussion off the record.)

MR. STANOCH: What are you whispering to your counsel about, Doctor?

MS. LOCKARD: He asked me to remind him of your name, and I said Stanoch.

THE WITNESS: I'm sorry. I had a senior moment.

MR. STANOCH: Oh, it's okay, Doctor. I wasn't going to call you out before, and I apologize I did now. It's a long day.

MS. LOCKARD: You are right. I should not be whispering. I should have done it louder.

MR. STANOCH: It's a --

THE WITNESS: Well, I apologize, too. I may be getting hypoglycemic.

Page 212

MS. LOCKARD: It is 12:45 here. I don't know, how long have been we been on the record, Ms. Videographer, can you say?

MR. HARKINS: Two hours since the last break.

MS. LOCKARD: Two hours since the last break, so let's ask the questions about this, and then --

THE VIDEOGRAPHER: An hour 35 since the last break.

MS. LOCKARD: You need a new watch.

BY MR. STANOCH:

Q. Let me know when you can see this exhibit, sir. I'm trying to screen-share now, if that helps as well.

A. Okay. I see the screen share.

Q. All right. And you see this is a Department of Justice announcement, May 13, 2013?

A. Yes, I do see this, and I'm familiar with this fine.

Q. Right. And you are familiar that the DOJ fined Ranbaxy, a generic drug manufacturer, 500 million relating to cGMP violations and false statements?

A. Yes, I do see that.

Page 213

Q. Right. And can you still see it?

A. I do see it, yes, thank you.

Q. Oh, good. I just wanted to make sure you were able to look at it. And you can look at this document all you want, sir, but the issue here is Ranbaxy, I think, was making generic Lipitor, and it was found to contain pieces of glass, right?

A. I would have to read more closely to see the pieces of glass, but I'll take your word for it. Go ahead.

Q. Okay. And so would you call generic Lipitor that contained pieces of glass AB-rated?

A. Well, we're getting into what causes the FDA to remove an AB rating. An AB rating relates to the review process. So, yes, I would say it's AB-rated.

Now, after it's in the market and you find something objectionable or it fails a specification or it's not in conformance with GMPs, it needs to be withdrawn from the market.

Q. So would you --

A. And that's what happened here.

Q. So would you consider Ranbaxy's generic Lipitor that contained pieces of glass adulterated prior to the date of its guilty plea?

Page 214

A. It's not my decision. It's an agency decision. Did the agency make a judgment of adulteration?
Q. Well, that's what I'm asking you, sir.
A. I don't see it here. If you can point it out to me, I would be glad to offer an opinion.
Q. Uh-huh. It says right there --
A. And I don't --
Q. -- in the first paragraph about the "distribution of certain adulterated drugs."
A. Yes, adulterated drugs, okay. So there the agency is making a decision that the drugs were adulterated.
Q. Right. And if you look on, you know, the next page here, "Ranbaxy USA admitted to introducing into interstate commerce certain batches of adulterated drugs that were produced at Paonta Sahib in 2005 and 2006." You see that?
A. Wait a minute. I'm trying to catch up with where you are reading. What paragraph are you in?
Q. Second full paragraph of the second page.
A. Oh. Yes, I see that. And your question, I'm sorry, is?
Q. Right. So you see here, right, that

Page 215

Ranbaxy admitted that it was selling batches of adulterated drugs produced at a facility in 2005 and 2006, right?
A. Yes.
Q. And that is, what, seven or eight years prior to its guilty plea per this notice of May 13th, 2013, right?
A. I'm trying to stay up with your dates. Okay. Yes, I see the dates you are emphasizing.
Q. Right. So Ranbaxy was pleading guilty that it was selling adulterated products for nearly ten years prior to the institution of regulatory action against it, right?
A. Yes. I see that.
Q. But it sounds like you are telling me that you would not consider any of that Ranbaxy product adulterated up and until the point where the FDA actually issued a warning letter; is that right?
A. No, the way I read this, I think Ranbaxy stated their drugs were adulterated in 2005, 2006, and that's an agency determination.
Q. Right. They retrospectively made that determination?
A. Well, I don't know if it is retrospective or not, but -- go on. I'll try to answer your

Page 216

questions.
Q. Right. The FDA said at a later point that the drugs you had been selling since 2005 were adulterated, right?
A. FDA can make a certain decision in time. But in this case, FDA made the decision when it issued the warning letters for ZHP and Mylan.
Q. Right. And it said in that decision that the valsartan API that you have been making up until this point is adulterated, correct?
A. No, I'm not agreeing with that.
Q. So --
A. I'm saying FDA had -- I'm saying Teva had recalled all product before the agency determination of adulteration.
Q. So the fact that Teva was selling product that the FDA later said contained adulterated API, you are saying that has no effect on whether or not Teva was selling adulterated products?
A. You know, I think we're confusing a lot of issues here. First of all, we have to look at the warning letters to ZHP and Mylan. And I'm glad to discuss those if you want to give them to me as exhibits.
But FDA made the general statement that

Page 217

products -- or drug substances produced at ZHP were adulterated within the meaning of the act because of GMP violations. I would have to see it. I'm not even sure it mentions nitrosamines --
Q. Uh-huh. Okay.
A. -- or the fact that the products containing nitrosamines were adulterated.
Q. Okay. Let's take out nitrosamines. So Teva selling valsartan that contained API that the FDA eventually said was adulterated because of cGMP violations has no impact on whether Teva's product was adulterated?
A. Well, I would -- is it possible to look at the ZHP warning letter?
Q. If you have a copy there, sir, go ahead. I don't know if I have it.
A. It's not in your exhibits?
MS. LOCKARD: We have a copy of it.
THE WITNESS: I don't think I cited it in my report. I don't think it's in a --
MS. LOCKARD: There is no question pending, so you don't have to answer.
BY MR. STANOCH:
Q. Uh-huh. Did you cite the ZHP warning letter from the FDA in your report, sir?

Page 218

A. I don't think it's in my materials cited. I don't recall seeing it there. And that's true also for Mylan. So --
Q. Okay. Well, we will figure that out. Let's put all this aside for now, and we can come back to it, but we want to go --
(Whereupon, a brief discussion off the record.)
THE VIDEOGRAPHER: Okay. We are going off the record. The time is 12:51.
(Whereupon, a brief recess was taken.)
THE VIDEOGRAPHER: Okay. We are coming back on the record. The time on the video monitor is 1:34. Please begin.
BY MR. STANOCH:
Q. Welcome back, Dr. Williams.
A. Thank you, Mr. Stanoch.
Q. During our lunch break did you speak with anyone besides your counsel there with you in San Francisco?
A. No, I didn't.
Q. Did you text or e-mail anybody about your testimony today?
A. No, not at all.
Q. And did you review any documents?

Page 219

A. We did not.
Q. Okay. Thank you.
Could you describe for me what it means that your expert report is only for class certification and not for liability?
A. My understanding is the liability litigation will occur later, and right now we're looking at class certification that relates to economic loss for individual plaintiffs and also large payors.
Q. Uh-huh. Right. And prior to the break we were talking a little bit about the Teva recalls, and I think you said that Teva had recalled all of its valsartan product from the market and has not reintroduced it, correct?
A. Yes, that's true, Mr. Stanoch.
Q. Okay. Are you aware of whether Teva has been undertaking to introduce a new generic combination product that includes valsartan?
A. You know, I believe in the course of some of my research or discussions with counsel, I did hear that. But I know very little about what they are doing, and it's certainly not in my report.
Q. Okay. I was going to say, do your opinions in any way relate to the fact that Teva is

Page 220

trying to market in the U.S. a new generic combination product that includes valsartan?
MS. LOCKARD: Objection. Foundation.
THE WITNESS: Was that a question, Mr. Stanoch?
BY MR. STANOCH:
Q. Yes. Did your opinions in any way relate to the fact that Teva is trying to market in the U.S. a new generic combination product that includes valsartan?
A. No, not at all.
Q. Uh-huh. Uh-huh. Do you think it would be pertinent to your opinions in this case if you were to eventually evaluate the testing and other parameters that Teva is applying for its new generic combination product that includes valsartan that it may introduce in the U.S.?
MS. LOCKARD: Objection. Confusing.
THE WITNESS: No, I can't see how that would have any impact on my report --
BY MR. STANOCH:
Q. Uh-huh.
A. -- and it certainly wouldn't change my opinions.
Q. Well, would you like to know what testing

Page 221

Teva is doing of this new product under development for nitrosamines?
A. I would always be interested in what Teva is doing because of their sophistication as a pharmaceutical company, but it doesn't relate to my report and it doesn't impact my opinions.
Q. Uh-huh. But if Teva is testing for nitrosamines now for a new product in ways that were available to it prior to 2018, that would be pertinent, would it not?
MS. LOCKARD: Objection. Speculation. Foundation.
THE WITNESS: Well, the way I would try to couch it in terms of my report is Teva should be following the 2021 guidance on nitrosamine impurities, and how they deal with those recommendations from FDA, as I say, would be of scientific interest to me, but not pertinent to my report.
BY MR. STANOCH:
Q. That's fair. Do you know whether Teva is following the FDA 2021 guidance on nitrosamine impurities regarding its development of a new valsartan combination product for the U.S. market?
A. Do I know what about that? I'm sorry.

Page 222

Q. Do you know whether Teva -- or strike that.

Do you know how, if at all, Teva is following the FDA 2021 guidance on nitrosamine impurities regarding Teva's development of a new valsartan combination product for the U.S. market?

A. No, I have no idea, and I'm sure Teva might regard that as confidential information.

Q. Uh-huh. You reference throughout your report, and we can look at particular paragraphs, pharmaceutically equivalent and bioequivalent; is that right?

A. Yes, I do speak to those points, Mr. Stanoch.

Q. Okay. And we can look -- you can look at any paragraph you like, but you can look at, say, Paragraph 60, where you mention both these terms, if that's helpful.

A. Okay. Thank you. I'll go to Paragraph 60. Okay. And that's on page 19?

Q. Yes. Are you there?

A. Yes, I am, sir.

Q. Okay. Now, what do you mean by "bioequivalent," as you use the term in your report?

A. Well, it's a requirement for a generic

Page 223

manufacturer to show bioequivalence between their proposed product and the reference listed drug. And it's expressed in law and regulations as an absence of difference in terms of the rate and extent of the generic product compared to the reference listed drug.

Q. What do you mean by the term "pharmaceutically equivalent" as used in your report?

A. Well, if you, again, look at the law and regulations, "pharmaceutical equivalence" means the same active ingredient; different impurities, possibly; the same dose form; the same strength; and the same route of administration.

So the two terms together, if they are met by a generic manufacturer, allow the agency to declare that the products are therapeutically equivalent, and if those requirements are satisfied, among other things, then FDA can give an AB rating in the Orange Book.

Q. And then I think in this paragraph, the second sentence, you explain what you mean by therapeutic equivalence; is that right?

A. Yes, and I may have gotten a little bit ahead of your questioning, but therapeutic

Page 224

equivalence means both pharmaceutically equivalent and bioequivalent.

Q. Uh-huh. Isn't it true, Doctor, that therapeutic equivalence includes pharmaceutical equivalence, bioequivalence, as well as having the same clinical effect and safety profile?

A. No, I wouldn't add that, Mr. Stanoch. I think the purpose of the bioequivalence study is to say the bioequivalence study substitutes for assessment of clinical safety and efficacy.

Q. Okay. Let's look at the next exhibit. Stand by.

This will be Exhibit 13. It's Tab 10 in your binder, sir.

(Whereupon, Exhibit 13 was marked for identification.)

BY MR. STANOCH:

Q. Let me know when you are there.

A. Okay. I'm looking at the Orange Book preface.

Q. Right. This is a copy of the Orange Book preface, correct?

A. Yes.

Q. And you are certainly familiar with the Orange Book, I take it, right?

Page 225

A. Yes.

Q. And what is the Orange Book?

A. It's an FDA publication entitled Approved Drug Products with Therapeutic Equivalence Evaluations. And then after that, we always say, "commonly referred to as the Orange Book." And the reason for that, it is an orange book.

I even know how it came to have the color orange. It was actually created around the time of Halloween, so that's why it's colored orange.

But it lists the FDA-approved products approved under the NDA/ANDA system.

I'll stop there, Mr. Stanoch.

Q. Okay. I appreciate that answer, including the color commentary on the Orange Book, Doctor.

If you can turn to the section 1.2, "Therapeutic Equivalence-Related Terms."

A. Yeah, I'm getting there. 1.1.

Okay. I'm there.

Q. And this section talks about certain terms. Do you see that?

A. I do.

Q. And one of those terms is "therapeutic equivalents," correct?

A. Yes. Under 1.2.

Page 226

Q. Yes. And could you just read us that first paragraph there for "Therapeutic Equivalents," where it says, "Approved drug products are"?
A. "Are drug products in identical dosage forms and route(s) of administration" and "contain identical amounts" --
Q. Oh, oh. Oh, oh, oh, oh, Doctor. I'm sorry to stop you. I was trying to direct you to the paragraph that is there for "Therapeutic Equivalents." Do you see that a little down?
A. Oh, sure. Down below?
Q. Yes. And just that -- it's three lines, the first paragraph. Do you see that?
A. Yeah, where it says, "Approved drug products"?
Q. Yes, sir. Could you just read that paragraph?
A. Sure. "Approved drug products are considered to be therapeutic equivalents if they are pharmaceutical equivalents for which bioequivalence has been demonstrated, and they can be expected to have the same clinical effect and safety profile when administered to patients under the conditions specified in the labeling."
Q. Right. And that second clause there that

Page 227

you read, that is something that is absent from your characterization of therapeutic equivalence in Paragraph 60 of your report, correct?
A. Yes. I think -- my hope -- everything is aligned and in agreement, but that is what I mean when I made those statements in Paragraph 60.
Q. And earlier I think you said that same clinical effect and safety is not part of therapeutic equivalence. Are you changing your testimony that you agree that a therapeutic equivalent can be expected to have the same clinical effect and safety profile when administered to patients under the conditions specified in the label?
A. Well, I think, without quibbling with you, Mr. Stanoch, what I was trying to say is in terms of the application process, the demonstration is the end of the sentence. And if those two types of equivalence are demonstrated, then, as you want to go on and say, they can be expected to have the same clinical effect and safety. But in terms of the concept of therapeutic equivalence, it stops with demonstration.
Q. Well, because I don't see anywhere in your report, doing a word search, and you can certainly

Page 228

look through it, that you don't mention anything about a therapeutic equivalent having the same clinical effect and safety profile.
A. Well --
Q. Why did you leave that part out?
A. You know, Mr. Stanoch, I have to say, it's an unimportant question. I think everybody knows that if you show pharmaceutical equivalence and bioequivalence, you then are allowed to have the same labeling as the reference listed drug, substantively, and this means you will have the same clinical effect and safety.
I don't know why you are questioning my words in my report, so perhaps you can explain that at the right time.
Q. Well, we can agree that your Paragraph 60 does not include the words "same clinical effect and safety profile," right?
A. No, and it's certainly understood, and I think any reasonable person would understand, what I meant when I talked about pharmaceutical equivalence and bioequivalence.
Q. So show me in Paragraph 60 where those words appear then, Doctor.
A. Which words?

Page 229

Q. "Same clinical effect and safety profile."
A. I don't say that. That's what therapeutic equivalence means.
Q. Uh-huh.
A. "Therapeutic equivalence" are the same words as "same clinical effect and safety profile."
Q. Uh-huh. Right. And those words do not appear anywhere in your report, though?
A. "Therapeutic equivalence" appears there, and it means the same thing as identical safety and efficacy outcomes. That's what it means to have the same labeling as the reference listed drug.
Q. Well, Doctor, I want to make sure we're not talking past each other. I'm looking at your Paragraph 60, and it says, "Therapeutic equivalence means that the drug is pharmaceutically equivalent and bioequivalent for the same use," period; is that right?
A. Mr. Stanoch, I just really am not following your line of questioning. Can you be more clear?
Q. Oh, absolutely, Doctor. I'm looking at the words you wrote.
A. I think I'm --
Q. So let's look at Paragraph -- go ahead.

Page 230

A. Mr. Stanoch, let me finish my answer.
Q. Please.
A. I think I am perfectly clear here. Anybody would understand what I'm saying who understands generic substitution. Now, what is it about my statement or my words that you are not getting?
Q. I'm getting it about the words that are not there, Doctor, that's my first step. I'm looking at Paragraph 60. Can we agree --
A. Well --
Q. Let me finish my question, Doctor, I let you finish your answer, please.
Your Paragraph 60, when you're defining therapeutic equivalence, you say, "Therapeutic equivalence means that the drug is pharmaceutically equivalent and bioequivalent for the same use," period, correct?
A. I don't think you are reading my words correctly.
Q. Well, you turn to Paragraph 60, Dr. Williams.
A. Would you please try to read my words correctly?
Q. Why don't you read Paragraph 60 to me,

Page 231

Dr. Williams?
A. All right. I'll be glad to. "Generic drugs that are pharmaceutically equivalent and bioequivalent to the" reference listed drug and "are deemed therapeutically equivalent and are interchangeable with the" reference listed drug. Now, what part of that don't you understand?
Q. Please keep reading, Doctor.
A. "Therapeutic equivalence means" "the drug is pharmaceutically equivalent and bioequivalent for the same use." We're talking about the labeling. In other words, if you're pharmaceutically equivalent and bioequivalent, you get to use the same labeling as the referenced listed drug. If you have the same labeling, you will necessarily have the same clinical effect and safety profile.
I think these words are almost self-evident, and I really wonder why I haven't been clear about it with you.
Q. Doctor, I'm asking you to tell us where in Paragraph 60 you write that therapeutic equivalence can be expected to have the same clinical effect and safety profile?
A. I don't write it. I never said I did.
Q. And you don't write it anywhere in your

Page 232

report, correct?
A. I don't need to write it in my report. It's not pertinent. It's unnecessary.
Q. Uh-huh. And does valsartan containing nitrosamine impurities have the same safety profile as valsartan that do not have nitrosamine impurities?
A. Impurities are not a determinant of either pharmaceutical equivalence or bioequivalence, and that would include nitrosamine impurities.
Q. We're talking therapeutic equivalence now, aren't we?
A. I don't know. Is that your question?
Q. That's what we have been talking about, Dr. Williams. Let me ask it again.
Do you believe valsartan containing nitrosamines have the same safety profile as valsartan that does not contain any nitrosamines?
A. Okay.
MS. LOCKARD: Objection. Form of the question. Vague.
THE WITNESS: That is a different question. And I would say, with appropriate limits, yes, the answer to your question is yes.

Page 233

BY MR. STANOCH:
Q. Well, what do you mean by "appropriate limits"?
A. Well, for example, the interim limits that FDA set in December 2018 for --
Q. In absence of those limits, do you believe valsartan containing nitrosamines has the same safety profile as valsartan that does not contain any nitrosamines?
A. Are you asking my personal opinion? Or are you asking me as part of my report?
Q. You are the one opining on therapeutic equivalence, Doctor, so I'm asking you, both in your opinions and in your personal knowledge.
A. I would say it would have the same therapeutic outcome in terms of safety and efficacy. If somebody wants to give data that suggests otherwise, the FDA could look at that data.
Q. Uh-huh. You are talking about therapeutic outcomes, you are referring to whether the drug works for its intended purpose, right?
A. I would say when we look at these words, yes, we are talking about the valsartan molecule.
Q. Right. And still the issue we're trying to get at here, Doctor, is: In the absence of

Page 234

interim limits, do you believe valsartan containing nitrosamines, which you have agreed is part of the cohort of concern, has the same safety profile as valsartan that does not contain nitrosamines?

A. Well, let's back up a little bit. First of all, we understand that the impurity profile can be different in the drug substance of the generic compared to the reference listed drug. And there could be many, many impurities in those two drug substances with unknown pharmacologic effects.

When you see a particular impurity of concern, you would like to put a limit on it, including whether it's a genotoxic impurity or not. That's the whole idea behind reporting, identification, and qualification.

I think nitrosamine impurities here are part of the general approach to impurity handling. So I would say if nitrosamine impurities are handled the way other impurities are handed in the world of generic substitution, yes, you would get the same safety and efficacy outcomes.

Q. What if they are not handled in the way other impurities are handled?

A. Well, if I don't -- can you be more specific in your question in terms of how they would

Page 235

be handled differently?

Q. Sure. Prior to June 2018, assume there is valsartan that contains nitrosamines and valsartan that does not contain nitrosamines. Do they have the same safety profile?

A. We just don't know that.

Q. So then how --

A. I mean, for all I know, the valsartan drug substances that contain nitrosamine may have been at perfectly safe levels. I just don't know that.

Q. Uh-huh.

A. FDA finally decided they need to be below certain interim limits. But even there, I think FDA would say the risk was very low and that their limits were very conservative. So you are asking a question that would be very difficult to answer.

Q. Uh-huh. Well, in the real world, Doctor, right, if you go to a patient and you say to the patient, do you want this valsartan that contains nitrosamines or do you want this valsartan that does not contain nitrosamines, what do you advise your patient?

MS. LOCKARD: Objection. Outside the scope of his expertise.

THE WITNESS: I would say nitrosamines are

Page 236

commonly found in foodstuffs and they can be allowed in chemically synthesized drugs at certain levels. And the goal here of this whole effort really has been to identify them and make sure they do not exceed those levels.

BY MR. STANOCH:

Q. Would you advise patients to keep taking recalled valsartan products?

MS. LOCKARD: Objection. Speculation. Outside the scope.

THE WITNESS: Well, that seems a very odd question since they were recalled. Is that a hypothetical?

BY MR. STANOCH:

Q. Well, we are just trying to say what you would do with a patient, Doctor. And by the way, you are a doctor, correct?

A. That's right.

Q. You have an active medical license, correct?

A. I do not.

Q. You do not. When was your medical license last active?

A. In 1990. I stopped treating patients clinically when I went to FDA in 1990.

Page 237

Q. Uh-huh. Uh-huh. And would you advise a patient, if given the choice, to take valsartan that contained nitrosamines or valsartan that did not contain nitrosamines?

MS. LOCKARD: Objection. Outside the scope of his expert report and opinions.

THE WITNESS: You know, it's a hypothetical. I'm going to give you an answer that may not seem appropriate.

But I worked once with a very sophisticated chemist at FDA who said you get more impurities in the back of a Washington, D.C., bus than you will ever get from your medicines.

So, you know, it's a question of risk, relative risk, severity of risk, and I just don't think I can answer your question.

BY MR. STANOCH:

Q. You have a -- oh, sorry. Go ahead.

A. I would say to patients, FDA will control impurities within the -- nitrosamine impurities within your medical products appropriately in accordance with the new guidance.

Q. Uh-huh. Prior to the FDA guidance in December 2018, right, would you advise a patient to take valsartan with nitrosamines or the valsartan

Page 238

without nitrosamines?
A. Well, let me point out that FDA told people to keep on taking their valsartan products before the interim limits were set.
Q. And that was so they don't drop dead of a heart attack, correct?
MS. LOCKARD: Objection. Speculation.
THE WITNESS: I would not say that it way.
BY MR. STANOCH:
Q. Right. Because they did not want to go off your medication for hypertension abruptly until you had a substitute; isn't that right, Doctor?
A. Well, they did not want people to abruptly stop their medicines containing valsartan.
Q. Absolutely correct. But don't you think the idea there was: Don't abruptly stop, but you should probably get a different valsartan product or other substitute as soon as you can?
MS. LOCKARD: Objection. Speculation. Outside the scope of his expert testimony and this report.
THE WITNESS: I'll just stand by what FDA said. They said, don't -- you know, the risk here is very low. The recall classification risk was low. And they were saying, don't stop your

Page 239

valsartan medicines abruptly under these circumstances.
BY MR. STANOCH:
Q. Uh-huh. All right. So let's go back to the safety profile one more time, Doctor. You are not going to tell us whether you think a valsartan with nitrosamines might have a different safety profile than a valsartan without nitrosamines?
A. I absolutely don't know, and to answer that question would be a very difficult comparative clinical trial.
Q. Uh-huh. Well, let's say right now with -- let's say today --
MS. LOCKARD: Wait. Hold on a minute. Let him --
BY MR. STANOCH:
Q. Oh, go ahead, Doctor.
A. And if you think about what it would take to answer that question, imagine a comparative clinical trial where you have patients randomized between two valsartan-containing products, one with one limit set by FDA and one with no limits before FDA set limits. Imagine the outcome of that clinical trial. I think it would be very hard to see a difference.

Page 240

Can you imagine how many patients you would have to study to see a difference even if it existed?
Q. Let's talk about today, right. The FDA limits for nitrosamines exist today, right?
A. Yes.
Q. Does a valsartan drug that contains nitrosamines above those limits have the same safety profile as a valsartan drug with nitrosamines below those limits?
A. Far as I know, they have the same safety and efficacy outcomes.
Q. So then what is the point of the interim limits, then, which say, if you have more than this, you can't sell it?
A. You have to set some kind of limits. That's what an impurity is. An impurity needs a limit.
Q. But you just said, Doctor, that a valsartan product with nitrosamines above the limits as they exist today is just as safe as one that has nitrosamines below the limit, didn't you?
A. I have no understanding that it has a different safety profile in terms of any kind of risk.

Page 241

Q. If not for safety, Doctor, then why is the FDA setting limits for nitrosamines in the first place?
A. They need to set a limit for the impurity, and they base it on that M7 guidance in terms of how you set limits for genotoxic impurities.
Q. Which is --
A. Remember, it's a very difficult decision because nitrosamine impurities are present in food and foodstuffs and in the environment, in the water. And you saw it in the M7 guidance. How do you set limits when that kind of impurity is present all around us, if you will?
FDA has to do something. They do it out of an abundance of caution. But it doesn't mean that something above the limit was therefore toxic.
Q. You can't sell a product today that is above the nitrosamine limits, correct?
A. Well, I'll generally agree with you, but I will also say that in the guidance they say you can be above limits under certain circumstances with FDA approval.
Q. Are you aware of any manufacturer who has sought FDA approval to sell a product with nitrosamines above the now-current limits?

Page 242

A. No, I am not.
Q. Uh-huh. And you are telling me that the FDA limits on nitrosamines have nothing to do with the safety of the drug; is that your testimony today, sir?
A. I think they have to do with reducing risk, and that is how FDA would state it in terms of the M7 guidance and also the nitrosamine guidance.
Q. Risk of what?
A. But that risk is very difficult to quantify.
Q. Risk of what?
A. Risk of whatever a nitrosamine impurity might do.
Q. Uh-huh. What might it do?
MS. LOCKARD: Objection. Speculation. Outside the scope of his opinions.
THE WITNESS: I'm sorry. Was that a question, Mr. Stanoch? I didn't hear it.
BY MR. STANOCH:
Q. Yes, sir. What might it do, the risk?
A. Well, you can see it in the M7 guidance, that it has the propensity in certain settings to cause cancer.
Q. Right. Right. The purpose of the FDA's

Page 243

limits currently is because there is a risk, however quantified, to a patient if they take a pill that has nitrosamines above the limit, right?
MS. LOCKARD: Objection. That's far outside the scope of his opinions. He's not giving a causation opinion.
THE WITNESS: Yeah, I am not definitely not getting into causation.
BY MR. STANOCH:
Q. I'm not asking you either that, Doctor. What we're trying to understand here now is the safety profile of a drug that has nitrosamines above the limit. And you were telling me, correct me if I'm wrong, that it has nothing to do with safety, correct?
A. No, I'm saying I don't know if there is a difference between the safety profile of the two products.
Q. So --
A. It may be exactly the same, and to prove that it's different would take a lot of work. That's my point.
Q. Uh-huh. So you are saying that a valsartan drug with nitrosamines above the current limits may be just as safe as a valsartan product

Page 244

with nitrosamines below the limit or quantified at zero?
MS. LOCKARD: Objection. Outside the scope of his opinions.
THE WITNESS: I'm saying that hypothetically that could easily be possible.
BY MR. STANOCH:
Q. Uh-huh. Okay. Let's look at the exhibit some more. The next paragraph, do you see where it reads, "FDA classifies as therapeutically equivalent"? Do you see that?
A. Yes.
Q. And then it lists a number of criteria which the Orange Book says the FDA classifies for purposes of therapeutic equivalence, right?
A. Yes. Are you reading that final paragraph on this page?
Q. Yes, sir. The sentence reads, "FDA classifies as therapeutically equivalent those drug products that meet the following general criteria"; do you see that?
A. Yes, I do, and then it goes one, two, three -- I guess the last one is four -- five. It continues on, and I think it ends with five.
Q. Yes, sir. I agree with that.

Page 245

And these are criteria that the Orange Book reports that the FDA uses for classifying drug products as therapeutically equivalent, correct?
A. Yes.
Q. All right. And one of those is Number 5, is whether the drug product is "manufactured in compliance with Current Good Manufacturing Practice regulations," correct?
A. Yes, I see that.
Q. And another one is 2(b), which is that the drug products "meet compendial or other applicable standards of strength, quality, purity, and identity"; did I read that correctly?
A. Yes, you did.
Q. Right. So for therapeutic equivalence, meaning compendial standards alone may not be sufficient per the Orange Book's guidance, correct?
A. That's quite true, because sometimes there isn't a compendial standard, so in that case there would be a private, FDA-agreed standard.
Q. Uh-huh. And there may be other examples as well, correct?
A. Well, I don't know what you mean by that. I'm thinking of the case where there is no compendial standard.

Page 246

Q. Uh-huh. And there may be standards reflected in ICH or other industry guidance, correct?
A. No, I wouldn't go there. I'm trying to think of a simple case, that many times FDA doesn't have a monograph for a drug substance or a drug product --
Q. Uh-huh.
A. -- in which case, the quality would be controlled with a private specification agreed to with FDA as part of the review process.
Q. Uh-huh. This criteria 2(b) does not say anything about the absence of a compendial standard, correct?
A. Well, I think it does. It says, "meet compendial or other applicable standards."
Q. Uh-huh.
A. The other applicable standards would be the private specification agreed to with FDA.
Q. Uh-huh. And I think you testified about this earlier, that a manufacturer can agree to different specifications or standards for a drug in consultation with the regulator, right?
A. Yeah, I think that's generally part of what I'm saying here.

Page 247

Q. Then let's flip a few more pages. Unfortunately it's not numbered, Doctor. This is the section that has 1.7, "Therapeutic Equivalence Evaluation Codes." Tell me when you are there.
A. Okay. I'm there.
Q. And if you look at the first paragraph of that page, it begins in bold, "Every product in the Orange Book is subject at all times to regulatory action." Do you see that?
A. Yes, I do, at the very top of the page.
Q. And you can read that full paragraph if you like, but I want to direct your attention to the penultimate sentence that begins, "FDA believes that retention"; do you see that?
A. Yes, I do see that.
Q. Could you just read that sentence, just that sentence, sir?
A. "FDA believes that retention of a violative product in the Orange Book will not have any significant adverse health consequences, because other legal mechanisms are available to the Agency to prevent the product's actual marketing."
Q. Thank you. And that means, does it not, that just because a drug is listed in the Orange Book, does not mean that it's immune from being

Page 248

found to be adulterated or otherwise improperly marketed, right?
A. Yeah. I think what we're getting at here, too, is the idea that there can be recalls if a product fails its specifications, and that happens all the time, as I stated in my report. That doesn't mean it will be taken out of the Orange Book or its AB rating will be changed. I think that's what we're talking about here.
Q. You can put that aside for now.
(Whereupon, a brief discussion off the record.)
BY MR. STANOCH:
Q. Are you aware of whether Teva has a master drug file for valsartan?
A. If I understand your question, Mr. Stanoch, are you saying Teva makes its own valsartan?
Q. Right. Do you understand Teva to have a drug master file for valsartan?
A. Yes, thank you.
No, I am not aware of that. I would think it would be possible.
Q. Would seeing documents related to Teva's own valsartan DMF be pertinent to you in terms of

Page 249

whether Teva could have known about nitrosamines forming as part of the API manufacturing process for valsartan?
MS. LOCKARD: Objection. Lacks foundation.
THE WITNESS: I wouldn't rule it out, but I don't think -- I didn't see any documents like that.
BY MR. STANOCH:
Q. Uh-huh. Stand by.
Could you turn in your report, sir -- it's beginning around Paragraph 120, the first Paragraph 120. I think it's around page 41. I don't have the exact copy you have in front of you.
A. 120?
Q. Yes, sir.
A. On page 41?
Q. Yes.
A. "Doctor Panagos asserts"?
Q. Yes. Are you there?
A. Yes, I am.
Q. Great. And in this subsection, you're rebutting, if you will, opinions offered by Dr. Panagos, correct?
A. Yes, I agree.

Page 250

Q. Right. And why don't you read the first couple sentences for us there in Paragraph 120?
A. "Dr. Panagos asserts that the safety and efficacy of a medication must be proven by the manufacturer to the FDA so that the medication may receive approval." I think it's a she. She "further states that this information serves as a warranty for the medication ensuring that it meets the quality standards outlined by" "FDA."
Should I stop?
Q. You can stop now.
A. Okay.
Q. And you picked up on part of it. You understand, you know, Dr. Panagos is a female, correct?
A. Yes, I see that now.
Q. Okay. If you can scroll down, sir, to Paragraph 123. Tell me when you are there.
A. Yes, I see that statement.
Q. Right. And it begins, "Dr. Panagos describes TPPs as payors at risk for purchases of affected valsartan containing drugs products."
A. Yes.
Q. And what are TPPs, as you refer to it there?

Page 251

A. I think Dr. Panagos uses that abbreviation for third-party payors.
Q. What is your understanding of a third-party payor in this case?
A. It might be an insurance company or -- you know, I'm trying to think of a term. You know, a medical care organization that pays for medicinal products.
Q. Uh-huh. Right. And then in the next sentence you talk about risk about stopping your antihypertensive treatment?
A. Yes.
Q. Right. You are talking about two different types of risk here in this paragraph, aren't you?
A. Well, I'm not sure I understand your question. Perhaps you could continue.
Q. Sure. So in the first sentence you are referring to TPPs as payors at risk, right?
A. Okay.
Q. Right. And then later you talk about, you know, risks of stopping antihypertensive treatment, right?
A. Yes.
Q. Right. So what I'm clarifying is: You

Page 252

are not saying that TPPs were at any sort of physical risk involving valsartan, right?
A. No, as I understand Dr. Panagos, she was referring to financial risk.
Q. Right. I would agree with that. You understand that TPPs are at financial risk for purchases of their, say, insureds, right?
A. Yes. And now I see your point. It is two different kinds of risks.
Q. Well, I appreciate your clarification. I think we're on the same page.
And then in the next paragraph, in the second sentence, you mention, "Both the TPPs and patients got value for these products up to the point they were recalled from the market." Do you see that?
A. Yes.
Q. What do you mean by "value" there?
A. Well, I think it gets to my general opinion that these were useful products. They were pharmaceutical equivalent. They were bioequivalent. They were AB-rated. And practitioners and patients used them successfully for the indications such as hypertension.
Q. Right. So are you opining on whether or

Page 253

not patients or TPPs received value for the valsartan they purchased prior to the recalls?
A. I think if you look at my concluding opinions, we have to pay attention to that.
Q. Of course.
A. My opinions are they were not adulterated. They were pharmaceutically equivalent and bioequivalent, and they were AB-rated. They were not misbranded.
Q. Right. I'm --
A. So I think I'm answering your question and speaking specifically to my opinions.
Q. Right. I'm looking at your conclusions, Doctor, at the very last page of your report, and I don't see anything about opinions on who might have received what value for valsartan products, so that's what I'm trying to understand here.
A. I guess if I wanted to extend my conclusions, my opinions to this particular paragraph, I would say third-party payors got value.
Q. Uh-huh. And again, you define the value that the third-party payors got as what?
A. In terms of getting a safe and effective product that could be used to treat patients in accordance with labeled indications.

Page 254

Q. And you are including in your definition of a safe and effective drug products that have nitrosamines in them, right?
A. Yes. And we know the products can have nitrosamines in them.
Q. Including products that had nitrosamines above the FDA's eventual limits, correct?
A. Well, that's the debatable point, and I'm saying I just don't know if they had any different safety and efficacy compared to the products below that limit.
Q. Got it. You are not a -- you don't know one way or the other whether a valsartan drug that contains nitrosamines above the now-current FDA limits had a different safety profile than valsartan with nitrosamines below the now-current limits?
A. I think you are stating that correctly, Mr. Stanoch.
Q. Uh-huh. Do patients have a choice when it comes to the drugs that they are prescribed?
MS. LOCKARD: Objection. Speculation. Outside the scope.
THE WITNESS: Well, they can certainly talk to their doctors, and FDA encourages that, of course. I would encourage it if I were at FDA. And

Page 255

I would say, yes, they do have a choice.
BY MR. STANOCH:
Q. But they would have no way of knowing, would they, about whether the valsartan they received prior to the recalls contained nitrosamines or not, right?
A. Well, I'll make the general statement that I don't think any label for a new drug approved by the NDA or ANDA process has information about impurities on the label.
Q. Uh-huh. So then based on the -- valsartan's labeling part of the recalls, there is no way a consumer would be able to make a decision as to whether they wanted a valsartan product that did or did not contain nitrosamines?
A. The only way they would know in this particular instance is to read the FDA press releases and talk to their physicians and pharmacists.
Q. Right. And prior to those FDA press releases, there was no way for them to know based on the labeling alone?
A. Well, I think that's generally true, but I'm not sure entirely.
Q. Okay. Let's mark another exhibit. Stand

Page 256

by, Doctor.
(Whereupon, Exhibit 14 was marked for identification.)
BY MR. STANOCH:
Q. This is Exhibit 14. It should be Tab 32 in your binder. Tell me when you are there, sir.
A. Yes, I see this. Begins, "Expert: Nitrosamines 'Can Slip Through.'"
Q. Correct. It's an article in Pharmacy Times from June 29, 2021. Do you see that?
A. Yes, I do see it.
Q. And it says it includes a discussion with "Edwin Gump, Ph.D., vice president of the Small Modules Department at U.S. Pharmacopeia (USP)." Do you see that?
A. Yes, I do see that.
Q. Are you familiar with Dr. Gump?
A. No, I'm not.
Q. Are you familiar with the Small Molecules Department at USP?
A. Yes, I think I would -- I am familiar with that.
Q. Uh-huh. And then if you want to -- if you would flip to the third page of this document, sir. Tell me when you are there.

Page 257

MS. LOCKARD: You can -- to review it if you need to.
THE WITNESS: Yeah, I'm looking at the whole document just a second. It appears to be an interview between a reporter, Alana, and Dr. Gump in a publication for Pharmacy Times. So you want me to go to the third page? One, two, three?
BY MR. STANOCH:
Q. Yes. Yep.
A. At the top it starts with, "class"?
Q. Yes, sir. If you could --
A. Okay. Got it.
Q. Great. If you can go on that page down, do you see the bolded name of the reporter, "Alana"; you see that?
A. I do see that.
Q. Uh-huh. And she asks, "Right. Why are nitrosamines of such particular concern?" You see that?
A. Yes, yes.
Q. And why don't you read Dr. Gump's response to that question, that first paragraph there, beginning, "So"?
A. "So, I'm not a toxicologist, but nitrosamines, from my reading, these are compounds

Page 258

that have been studied for a number of years. There's at least a number of compounds in this class that are known mutagenic carcinogens. So, they're basically fairly nasty cancer-causing actives."

Should I stop there?

Q. Yes. That's fine. I can ask questions on that.

So do you agree with Dr. Gump that nitrosamines are fairly nasty cancer-causing actives?

MS. LOCKARD: Objection. Outside the scope of his expert opinion in the class-certification phase. You are asking him causation opinions.

THE WITNESS: Well, I guess what I would agree with is Dr. Gump says he is not a toxicologist, and neither am I, so I agree with him there.

BY MR. STANOCH:

Q. So would you agree with him that nitrosamines are fairly nasty cancer-causing actives?

MS. LOCKARD: Objection. Outside the scope of his testimony. Asked and answered.

THE WITNESS: You know, I don't agree with

Page 259

him there. That seems to be a fairly off-the-cuff comment that would take a very sophisticated expert to speak about the clinical impact of a particular nitrosamine impurity.

BY MR. STANOCH:

Q. Uh-huh. Then would you agree with Dr. Gump that nitrosamines are compounds that have been studied for a number of years?

A. Yes, I think that's true. I would agree with that.

Q. Uh-huh. Okay. Then why don't you move to the last paragraph of that same page? It reads, "But the one place."

A. "But the one place that people don't really have a choice -- you can choose not to eat that grilled burger -- but people shouldn't have to make a choice" to "have concerns about the quality of their medicines."

Q. Right. Do you agree with that statement from Dr. Gump?

A. Well, again, these seem kind of very general, unscientific statements. I mean, people shouldn't have to make a -- can choose not to drink your water that has nitrosamines. Does he want to say that, that people should not drink their water?

Page 260

I mean, these are very general statements, but I don't have a particular opinion about them, and they don't relate to my report.

Q. Well, respectfully, sir, you are opining on the value received from the drugs that are at issue here. And I'm asking you, then, here if you agree with Dr. Gump from the USP Small Molecule Department about whether people don't really have a choice when it comes to their drugs as opposed to different foodstuffs and other things.

A. Is it --

MS. LOCKARD: There is not a question pending.

THE WITNESS: I just don't understand the question. I mean, was there a question? Could you rephrase it, perhaps, Mr. Stanoch?

BY MR. STANOCH:

Q. Do you agree that people can choose not to eat their grilled burger, but people shouldn't have to make a choice or have concerns about the quality of their medicines?

MS. LOCKARD: Objection. Vague. Outside the scope of his testimony for class certification.

THE WITNESS: And, you know, just continuing on, you know, we can certainly

Page 261

cherry-pick statements out of this, but on the next page it says, "The U.S. medicines supply is probably the safest, or safe as any in the world, and we want to make sure that the public really feels confident" about "when they need to take a medicine that they can do so and not have other things they have to concern themselves about like nitrosamines."

I can certainly agree with that.

BY MR. STANOCH:

Q. You are agreeing to a different statement that I didn't ask you about; is that what you just did, Doctor?

A. Well, you are asking me to read at the bottom of -- maybe I misread where you asked me to read. If so, I apologize.

Q. Well, we have been at the same page, Doctor.

A. Well, maybe I skipped over a page. Yes, you had me read at the bottom of page 3; is that correct, Mr. Stanoch?

Q. Yes, sir.

A. Yes, okay. I'm sorry. I jumped ahead.

Q. Again, do you agree with Dr. Gump's statement in that paragraph, "But the one place that people don't really have a choice -- you can choose

Page 262

not to eat that grilled burger -- but people shouldn't have to make a choice or have concerns about the quality of their medicines"?

MS. LOCKARD: Objection. Vague. Outside the scope of the expert witness report on class certification.

THE WITNESS: If you are asking me if I agree with Dr. Gump, I have to say I don't because, you know, the presence of nitrosamine in food and water and foodstuff is very uncertain, and it's certainly not anything I talked about in my report. But I'm not sure people can choose their foods and their water so that they avoid nitrosamines. I just don't know that.

Maybe he could make that point with regard to a grilled burger, but what about all the other grilled products and all the other foods that have nitrosamines? It's a very general, if I may say, uninformed statement, so that's why I am hesitating to agree with it.

BY MR. STANOCH:

Q. So you don't agree?

A. I certainly agree that we need to control nitrosamines in our medicines, and that's what this entire effort, which began in 2018, is all about.

Page 263

Q. Are you aware of any efforts to control nitrosamines in drug products prior to 2018?

A. I am not aware of that, Mr. Stanoch.

Q. Uh-huh. Would that be pertinent to the opinions you are offering currently in this case?

A. I think it is generally in the sense that science marches on, FDA marches on, drug regulation gets better. We have many, many examples of that in the United States.

And is it perfect? Are drugs perfect now? No. But we can hope that in 10 or 20 years they will be better than they are now. And what we see happening here is an example of that happening with regard to valsartan and nitrosamines.

Q. So you agree, then, that if information was made known to a API manufacturer prior to the 2018 recalls about the potential for nitrosamine impurities, that that should have been something that was dealt with at that time, correct?

MS. LOCKARD: Objection. Vague.

THE WITNESS: I can't agree with it. It does seem very vague. Perhaps you can restate the question.

BY MR. STANOCH:

Q. Well, it sounds like you are saying nobody

Page 264

knew about nitrosamines until the summer of 2018, right?

A. That's what FDA says. I'm not saying that.

Q. Uh-huh. Well, you are opining that allegedly the FDA said it was unexpected and nobody knew about it until summer of 2018, right?

A. Yes, FDA made a series of statements along those lines.

Q. Right.

A. And it's definitely a part of my report.

Q. It certainly is. I can agree with that.

And then once the information came to light about the nitrosamine impurities in valsartan, the regulators in the industry took action, right?

A. Well, there was a series of events that now have extended over the past four years and extends to all the chemically synthesized drugs in the country. So I guess you could say it's a very comprehensive set of activities.

Q. And if that series of events -- oh, strike that.

And if the information about nitrosamine impurities in valsartan came to light earlier, that series of events would have started earlier,

Page 265

correct?

MS. LOCKARD: Objection. Vague.

THE WITNESS: I suppose you could make that hypothetical, and I wouldn't debate you.

BY MR. STANOCH:

Q. Let's flip to the fourth page of the article in front of you, Doctor.

A. One, two, three, four. Okay. Is this the page that starts at the top, "ones that" "need"?

Q. Correct, sir. If you can go down to the paragraph where Mr. Gump's name is bolded again, and it begins, "That's a great question." Do you see that?

A. Yes, Dr. Gump, "That's a great question."

Q. Right. And then can you read the next sentence?

A. "So, I think I mentioned that manufacturers have a responsibility to evaluate their processes and their products and look for chance where they could have a risk of nitrosamines."

Q. Do you agree with that statement?

A. Well, certainly, because Dr. Gump is echoing the FDA guidance that came out well before this interview --

Page 266

Q. Uh-huh.
A. -- particularly in February 2021, and this is the end of June 2021.
Q. Uh-huh.
A. Dr. Gump, if I may say so, is on very safe ground.
Q. And would --
(Reporter clarification.)
THE WITNESS: Safe ground, S-A-F-E.
BY MR. STANOCH:
Q. Would you agree that prior to summer of 2018 manufacturers had a responsibility to evaluate their processes and their products to look for the chances of genotoxic impurities?
MS. LOCKARD: Objection. Outside the scope.
THE WITNESS: Yes, I think that is what the guidance that we looked at before speaks to, and that had a date -- I guess it was a final date of 2018.
BY MR. STANOCH:
Q. You are referring to the ICH guidance, correct?
A. Yes, the M7.
Q. Right. And then there were prior

Page 267

iterations of that same guidance, right?
A. Yes. And other guidances, too, an ICH guidance and, I believe, an EMA guidance.
Q. Uh-huh. And manufacturers would have responsibilities to evaluate their processes and products for genotoxic impurities under the prior iterations of the ICH and EMA guidance, whatever they may be at that period of time, right?
A. Yes, and there are certainly other statements in Dr. Gump's interview that we could look to. But I'll wait for your questions, Mr. Stanoch.
Q. Okay. Very good. So why don't we actually put that aside for now, Doctor.
Some other questions about your professional experience, sir.
A. Yes, please.
Q. You are not a Pharm.D., correct?
A. I am not.
Q. Have you ever dispensed a drug?
A. I have not.
Q. Have you ever prescribed any valsartan or Diovan?
A. I have not.
Q. Have you prescribed any drug since 1990?

Page 268

A. You know, actually, I haven't. I don't write prescriptions.
Q. Do you know what a pharmacy and therapeutics committee is?
A. I do.
Q. Okay. And what is that?
A. Well, I would say it's a group of experts that build a formulary for a defined benefit offered to a community. So, for example, a hospital, a big hospital in an inner city may have a P&T committee that builds a formulary that the physicians and pharmacists in that community can use to write and dispense drugs -- write prescriptions and dispense drugs.
Q. We can call that pharmacy and therapeutics committee a P&T committee, right?
A. Yes, sir.
Q. Have you ever served on a P&T committee?
A. No.
Q. Have you ever consulted with any P&T committee?
A. Well, I remember during my days at USP I met with the Kaiser P&T committee to discuss how they work, but I wouldn't call that a consultation.
Q. Okay. The --

Page 269

A. They weren't asking my opinion. It was more an exchange of information.
Q. Fair enough. And roughly when was that?
A. Oh, gee. 2010.
Q. 2010. Have you ever been asked by any third-party payor to consult on their formulary designs?
A. No. But I should mention perhaps at this point that USP was asked to consider model guidelines for formularies as part of the Medicare Part D benefit. And that was a large effort for the organization when I was there, and as far as I know, it's still continuing.
Q. Were you part of that effort while you were working at USP?
A. Yes, as a matter of fact, I chaired an expert committee which created the first model guidelines, and that was a very interesting effort.
Q. Uh-huh. And what are the name of the guidelines?
A. I would call them the USP model guidelines for the Part D -- to assess Part D formulary plans.
Q. Uh-huh. You are not opining here, Doctor, about what information a P&T committee relies on when making decisions about reimbursements for drug

Page 270

products, correct?
A. No, I am not.
Q. All right. Have you ever worked for a third-party payor?
A. I have not.
Q. Do you know what a PBM is?
A. It's a pharmacy benefit manager.
Q. Have you ever worked for a PBM?
A. No, I have not.
Q. Have you ever consulted with a PBM professionally?
A. No, I haven't.
Q. Right. You are not here to opine on anything a PBM might rely on when it's making any determinations regarding a pharmacy benefit, correct?
A. No. No. I don't believe that's any part of my opinions.
Q. Okay. Let's mark another exhibit. Stand by.
(Whereupon, Exhibit 15 was marked for identification.)
BY MR. STANOCH:
Q. This is Exhibit 15. It should be Tab 31 in your binder, sir. Just let me know when you are

Page 271

there.
A. I think it's coming toward me.
Okay. I see something called ProPharma Group.
Q. Right. And you can look through these pages, but this is all of the invoices that were produced to us for your work in this case. And if you can just look through them and confirm that this is the totality of the invoices for your work thus far in this case.
A. ProPharma. I'm a little confused about ProPharma Group. Oh, maybe I shouldn't be confused about that group. Okay, yes, I see these are my invoices, and these invoices should be concurrent until the end of January of this year. Okay.
Q. Right. I mean, the first few pages, I see the ProPharma Group, dated 11/30/21. Do you see that?
A. 11/30/2021, yes, I do see that.
Q. Right. And then the next few pages is for work from an invoice dated 12/31/21, right?
A. Yes, I submit my hours monthly.
Q. And then the next page after that is an invoice for your work through January 31, 2022, right?

Page 272

A. Well, wait a minute. I see a third page that looked like July 2021. Yes, that could be true.
Q. Right. Well, I guess there is a couple things here. First is: Why do some of your invoices say ProPharma Group and the other one at the end says NDA Partners?
A. My consulting group, NDA Partners, was sold in 2021 to a larger company called Planet Pharma, and then Planet Pharma in turn merged with ProPharma, so the overarching organization for my consulting group, which still exists as NDA Partners, is ProPharma Group.
Q. Got it.
A. And they do the billing.
Q. Did anyone at NDA Partners or ProPharma Group assist you in the preparation of your report that you submitted in this case?
A. No, not at all.
Q. Okay. You and you alone wrote your report?
A. Yes, I think that's quite true. I wrote this report.
Q. And the invoice at the end that is on the NDA Partners letterhead, it's dated 7/31/2021?

Page 273

A. Yeah, I think we may be looking at the transition from NDA Partners to ProPharma --
Q. Uh-huh.
A. -- so that's an interesting observation.
Q. And it looks like your first billed work in this matter was 7/1/2021, right?
A. That's when I was first contacted by counsel, and then there was a hiatus. I really didn't begin substantive work on this report until November. You can see that in the invoices.
And the reason I didn't do any detailed work in July until November was because I was not involved in the causation discussions.
Q. Then if you look on the ProPharma Group invoice dated 1/31/2022, the first entry is for work on January 3rd, 2022, correct?
A. Wait a minute. I'm having trouble catching up with you. But I'm setting aside the July one. Now there is one -- I see a July invoice. If that's what you are talking about, yes, I see that invoice.
Q. And just to go through this, a few things. You say, "Review 82 documents in triplicate." Do you see that?
A. Yes, I do.

Page 274

Q. What do you mean by "in triplicate"?
A. Well, I'm laughing a little bit because I think I got the same folder three times. I had to check with counsel many times to make sure that they were the same documents in the three folders. So that's what that was all about, and I did have a good review with counsel about the materials I received and where it was all filed.
Q. Uh-huh. And then further down here, you have some entries for, "Read DB deposition," "Read EG deposition"; do you see those?
A. Yes, those refer -- for example, "EG" refers to Elizabeth Gray. The "DB" refers, I believe, to Daniel Barreto.
Q. Uh-huh.
A. And then you can see Panagos expert reports.
Q. Uh-huh. And then that last entry, should that be DB deposition as well?
A. Well, I'm not sure about that. No, I think it may be a Binsol deposition.
Q. Uh-huh. So sometimes you listed the specific deposition you read, and sometimes you didn't, it looks like; is that right?
A. I could agree that the way I fill out my

Page 275

hours might not be entirely consistent.
Q. And I'm not going to take issue with that, Doctor. I just want to make sure, though, that even if you call out specific deposition transcripts here in your invoices, is it your position that you did review all the deposition transcripts that were in your materials considered?
A. No, I didn't look at all the depositions. I selected certain depositions that seemed particularly important.
Q. Which ones, then, did you review?
A. Well, we can see from this, I would say Daniel Barreto, Elizabeth Gray and Mr. Binsol. There may have been others, but I might have left them out of my invoice.
Q. Uh-huh. And if you flip back to the -- I guess the second page.
A. I'm trying to stay with you on page numbers.
Q. Well, I guess it -- yeah, I guess it would be page 1 of 2.
A. Is this December?
Q. Yes. December 31, 2021.
A. Yes, I'm looking at all that.
Q. Uh-huh.

Page 276

A. How can I assist?
Q. When you say, "Write CBE-30," are you referring to sections of your report?
A. Yes.
Q. Okay. You weren't writing a CBE-30 separately outside of your work, right?
A. Not at all. Oh, no, no, that would not be true.
Q. Uh-huh. And when you say, "Attempt to review ANDA files," what does that mean?
A. Well, ANDA, as you know, the ANDA files were very broad and deep and complex. So I would say I could review them from a high level, but I would not claim that -- I certainly wouldn't claim to counsel that I was reviewing the ANDAs in detail.
Q. Got it. And it looks that throughout all of your invoice work, your rate was the same, the $695 an hour?
A. Yes. And remember, that is what goes to the company. That's not what comes to me.
Q. Uh-huh. What portion do you get?
A. It's 80 percent.
Q. Okay. And you don't need a calculator, Doctor, unless you want it, but ballpark it looks like the invoices for your work to date for this

Page 277

matter is approximately $90,000 or so?
A. Yes. Let's say 80 percent of that would come to me, if we're calculating it that way.
Q. Understood. All right. You can put those aside for now. Thank you.
Can you pull up your -- I guess it would be Exhibit A to your report, sir. I'm looking at page 28 of 29 of Exhibit A. It's your prior deposition testimony.
A. Yes, I think it's coming to me. Just a second.
Q. Sure. Let me know when you are there.
A. Wait a minute. I have it in my CV here.
(Whereupon, a brief discussion off the record.)
THE WITNESS: I should have it in front of me. Hold on just a sec.
MS. LOCKARD: Here you go.
THE WITNESS: Oh.
Okay. I'm with you, Mr. Stanoch. Please proceed.
BY MR. STANOCH:
Q. Great. And here you have listed, it looks like, 14 matters in the last four years, right?
A. I'm counting 20, with the most recent

Page 278

being the trial testimony in November 17th. Are you cutting off some because they are not in the last four years?

Q. Oh, no, I'm sorry. The one I'm looking at -- maybe I have an older version in front of me -- only had 14 numbered entries. Let me look at something else.

A. It got cut off, but I see 20 in my CV in the final pages. But you may be right if we are just counting the last four years.

Q. Well, how many numbered matters do you have in the version that you are looking at, Doctor, 20?

A. I have 20, yes.

Q. Okay. And starting from the top of that, could you -- I just want to know what party you were retained by and in whose behalf you were offering opinions.

A. Oh, the first one I actually can't remember. I'd have to look it up to tell you.

The second one was sort of a -- it was a -- I could say it this way. It was a squabble between a lot of people. It really didn't have much -- it didn't have anything to do with FDA, really. And it was an individual where some people

Page 279

were complaining that he had taken intellectual property from a firm.

Supernus versus Actavis I think was a patent issue, and I was on the Supernus side.

The fourth one I think was antitrust.

The fifth one was a debate about a generic company versus Shire, and I was on the Shire side.

Solodyn was antitrust. I was on the part of plaintiffs.

Loestrin I think was antitrust, and that was on the part of plaintiffs.

Arbor versus ANI was sort of a company squabble, and I was on the ANI side.

Fresenius Kabi and Par was an argument about -- I'm summarizing very briefly, but I think it was restraint of trade, and I was on the Par side. They were the defendants, as I recall.

Galderma versus Teva was patent, and I was on the Teva side as the -- I'm struggling with what they were. Yeah, they got sued, so they were the defendant.

Belcher versus Hospira. I don't remember that one. I'd have to look it up. I apologize.

Continuing, Vision versus Sunrise, that was a sort of company squabble over GMPs.

Page 280

Restasis was antitrust.

Biogen was -- versus Acorda was related to an FDA guidance where I offered testimony.

Stewart, Sandoz was failure to warn.

Glumetza was antitrust, and that's still active.

Braeburn versus Camurus, that was a company squabble where I was on the side of Braeburn.

And then Ranbaxy is still -- I'm sorry. The Glumetza, I think, settled, and the Ranbaxy is still in progress, but it's antitrust. I'm on the side of the plaintiffs.

Genentech versus InterMune was patent. I was on the side of InterMune, the pioneer.

Mallinckrodt versus debtors, that was a squabble between third-party payors, if you will, and Mallinckrodt, and I was on the Mallinckrodt side.

Is that helpful, Mr. Stanoch?

Q. No, it is. I appreciate you going through that.

And, Doctor, for the prior cases you have offered expert opinions in, for those that are class actions, is it fair to say you have always been

Page 281

retained by a defendant in those actions?

A. You know, I'm not sure that I would identify any of those as class actions. I have to say I'm a little uncertain about just what a class action is, and so I couldn't say I was on one side or the other.

If you say an antitrust is a class action, I think I would agree with you that I'm usually on the side of plaintiffs, but I have one now where I believe it's antitrust and I'm on the side of the pioneer --

Q. But you just said --

A. -- so I don't think I can agree with you that I'm always on one side versus another.

Q. Uh-huh. But you are on the side of the defendants now in this case, right?

A. Yes.

Q. All right. And, the extent you remember, just go through and tell me where you think you were on the side of the defendants in your list of cases.

A. Oh, dear. Well, I'll give some examples. I think Mallinckrodt was the defendant. They were getting -- in Genentech I was on the side of the plaintiff.

Ranbaxy, I was on the side of plaintiff.

Page 282

Braeburn, I think they were the defendants.

At Stewart, I was on the side of Sandoz. That was the defendants.

Can't remember Biogen.

Restasis I was on the side of the payors, so they would be the plaintiffs.

I better stop there because I'm a little uncertain about my answers.

Q. Okay. If you are uncertain, that's okay, Doctor. I don't need you to guess. That's quite all right.

Stand by.

MS. LOCKARD: We have been going over an hour, so if you get to a good breaking point, that would be helpful.

BY MR. STANOCH:

Q. All right. Doctor, I just want --

MR. STANOCH: Yeah, we'll take a break soon, Counsel.

Q. Doctor, I just want to go back to your -- oh, what was it, Tab -- I think it was Exhibit 2. It was Exhibit 2, sir. It was the Roger Williams list of materials considered, 2/17/2022.

A. Yes, I have that before me, Mr. Stanoch.

Page 283

Q. And I want to make sure I understood this. So the materials listed here, you may or may not have looked at some of these things, but you are only relying on them for purposes of your report if they are cited in the body or footnotes of your report, right?

A. Yes, I think that's a fair summary.

Q. Fine.

MR. STANOCH: Let's take a break, then.

THE VIDEOGRAPHER: Okay. We are going off the record. The time is 3:00 p.m.

(Whereupon, a brief recess was taken.)

THE VIDEOGRAPHER: Okay. We are coming back on the record. The time on the video monitor is 3:35. Please begin.

BY MR. STANOCH:

Q. Okay. Welcome back, Doctor. During that lengthy break, did you talk to anyone besides your counsel?

A. No, not at all.

Q. Did you communicate with anyone besides the counsel in the room with you about your testimony?

A. No, not at all.

Q. Did you review any documents?

Page 284

A. No.

Q. Okay. All right. I'm going to mark, Doctor, a copy of the CV and your prior testimony in cases which was provided to me by Teva's counsel during the break that will be marked as Exhibit 16.

(Whereupon, Exhibit 16 was marked for identification.)

MR. STANOCH: So that should be available to everyone.

I will also mark at this time, as Exhibit 17, the video webinar from which the USP excerpt stills were taken.

(Whereupon, Exhibit 17 was marked for identification.)

MR. STANOCH: And I have no further questions at this time. I'll reserve my time pending counsel's questions. Thank you, Dr. Williams.

THE WITNESS: Thank you, Mr. Stanoch.

(Whereupon, a brief discussion off the record.)

EXAMINATION

BY MS. LOCKARD:

Q. Okay. Dr. Williams, a copy of your CV was just marked as Exhibit No. 16.

Page 285

Do you have a copy of that in front of you?

(Whereupon, a brief discussion off the record.)

THE WITNESS: Yes, I do.

BY MS. LOCKARD:

Q. All right. For the benefit of the jury and counsel, can you please give us the benefit of your educational background?

MR. STANOCH: Objection to form. Beyond the scope.

BY MS. LOCKARD:

Q. You can continue.

A. My undergraduate degree was a premed degree, and then after I completed my undergraduate studies, I went to medical school at the University of Chicago. I stayed on after my medical degree and obtained an internship and residency in internal medicine at the University of Chicago. And I received honors, both in undergraduate, Phi Beta Kappa, as well as medical school, called AOA, which is the equivalent of Phi Beta Kappa.

Then I entered the U.S. Army, and that was a deferred draft, where I stayed for three years. I actually did research on malaria at Walter Reed

Page 286

during the latter half of my service. In the first half I was stationed in Seoul, Korea.

When I finished that service, I entered a clinical pharmacology fellowship at the University of California, San Francisco. That lasted three years. And based on my training, I was able to obtain Board certification in both internal medicine and clinical pharmacology.

Q. Were you an officer in the Army?

A. Yes, I was a major.

Q. What licenses have you held?

A. I was licensed to practice medicine in California, but I didn't continue that or my Board certifications when I came to FDA in 1990 because it was a full-time job at FDA and I was not practicing clinical medicine.

Q. Have you held any licenses in pharmacology?

A. Clinical pharmacology. There is no licensure, but I was Board-certified in clinical pharmacology.

Q. What did you do when you left private practice or -- as a medical doctor?

MR. STANOCH: Objection to form.

Go ahead.

Page 287

THE WITNESS: I would say I was never in private practice. I worked at the University of California, San Francisco, doing clinical investigations for NDA and ANDA sponsors. And it was there that I built a focus on bioavailability and bioequivalence that I think has continued throughout my career.

I spent a year after my service at UCSF in a small company in South San Francisco that was studying an HIV medicine.

And then Dr. Carl Peck, who has been a very good mentor and friend, brought me to FDA in 1990 to head up the Office of Generic Drugs. And for those who may remember, that was a difficult time for both the generic industry and FDA. It had to do with something that briefly is called the generic drug scandal.

But I was very pleased to work in the Office of Generic Drugs. We worked with Congress and with industry to sort of straighten it all out. And I think we did get it straightened out. We sort of put it back on a solid footing. And the office has zoomed, if you will, ever since then over the ensuing decades.

In 1993, Dr. Peck left, so I came up to

Page 288

the level of the center, where I held multiple positions, but I ended my career and the last several years of my time at FDA working as a deputy director for the center director, who was Dr. Janet Woodcock at the time. Dr. Woodcock is now the commissioner of FDA on an acting basis.

And in my role as deputy center director, I had a lot of responsibilities, but I was principally the director of the Office of Pharmaceutical Science. That office is now the Office of Pharmaceutical Quality at FDA. And I had oversight for the Office of Generic Drugs, the Office of Clinical Pharmacology and Biopharmaceutics and the Office of Testing and Research and also the Office of Chemistry. So I had a terrific experience overseeing about four or five of the disciplines that contribute to the review of an NDA, as well as oversight for the Office of Generic Drugs and many other responsibilities.

I then left FDA in 2000. I became chief executive officer and chair of the Council of Experts. And I would say over my 14-year period there was a rapid expansion of USP, a globalization of our activities, a focus on the science of metrology, which I think is the undergirding science

Page 289

for what USP does, and the addition of a lot of compendia.

USP started out, when I was there, with USP-NF. Those are official compendia of the United States. But we added Food Chemical Codex, a Dietary Supplement Compendium. We even experimented with a novel compendium that we called the Medicines Compendium.

And overall it was a very remarkable experience, and I am forever grateful for having that experience.

Q. What --

A. After leaving USP, I became a consultant at the invitation of Dr. Peck again. Dr. Peck has been a great mentor, and he was the center director who brought me to FDA. And I have continued doing consulting in his consulting group, called NDA Partners, as we have discussed, and over the last several years I've focused primarily on litigation.

Q. How many years were you at the FDA, Dr. Williams?

MR. STANOCH: Objection to the form.

THE WITNESS: Ten.

BY MS. LOCKARD:

Q. How many years were you at the United

Page 290

States Pharmacopeial Convention, the USP?
A. Fourteen.
MR. STANOCH: Same objection.
BY MS. LOCKARD:
Q. What year did you leave the USP?
A. It was the beginning of 2014.
Q. And your CV that was marked as Exhibit 16, I was following along, but it has the dates and specific responsibilities and titles for your positions at FDA, USP and otherwise. Is that still accurate?
A. Yes, no changes.
Q. There are a number of honors and awards listed here in your CV. Are those still active?
MR. STANOCH: Objection.
THE WITNESS: Yes, no changes.
(Reporter clarification.)
THE WITNESS: No changes in those honors and awards.
BY MS. LOCKARD:
Q. Have there been any changes in your board memberships or research awards listed on your CV?
A. No, none. And I would say in my quasi retirement that's all been -- it's been replaced, if you will, by the litigation efforts.

Page 291

Q. Have you done any teaching work?
MR. STANOCH: Objection.
THE WITNESS: Yes, I would say at UCSF I taught pharmacy and medical students and also worked with graduate students on their Ph.D.s.
BY MS. LOCKARD:
Q. Have you served on any editorial boards?
MR. STANOCH: Objection.
THE WITNESS: I have been a reviewer for multiple journals and --
BY MS. LOCKARD:
Q. Any that would be relevant to this litigation?
MR. STANOCH: Uh-huh. A standing objection to background.
Go ahead.
THE WITNESS: Well, yes, I think all of my writings and research in one way or another relate to what we're talking about here in this, the quality of medicines, therapeutic equivalence, substitution, metrology, measurements. I feel everything in my wheelhouse, if you will, is related to this litigation.
BY MS. LOCKARD:
Q. Do you have any estimates in terms of how

Page 292

many journal articles you have contributed to?
A. Well, if you add all my publications, including the USP publications, I think we're well over 200.
Q. Have you participated in writing any books or book chapters?
A. Yes, I have done that.
Q. How many of those?
A. I think you would have to look at the CV, but I'm sure we're in the scores, maybe, or between 10 and 20.
Q. And are those journal articles and book chapters all listed on your CV, Dr. Williams?
A. Yes, I think the CV is complete.
Q. Oh, I would like to attach as Exhibit 18 a complete copy of your set of materials that we sent for your consideration. And we have been handed a thumb drive of that which we can get to the court reporter.
(Whereupon, Exhibit 18 was marked for identification.)
MS. LOCKARD: Exhibit 18, for the record, is going to be Dr. Williams' file.
MR. STANOCH: Counsel, this is everything listed in the -- what do you call it, the materials

Page 293

considered, Exhibit 2?
MS. LOCKARD: That's correct.
MR. HARKINS: Yes, yeah.
MS. LOCKARD: Yes.
MR. STANOCH: Okay.
MR. HARKINS: Also including the copy of the revised list of materials considered that was submitted with the production of those materials two days ago.
(Whereupon, a brief discussion off the record.)
BY MS. LOCKARD:
Q. All right. Dr. Williams, you were asked about a document we reviewed earlier today on a break that was identified as Exhibit 3, and it was the GNTM e-mail. Do you recall being asked about that?
A. I do recall.
Q. And did that document refresh your recollection about how Teva learned of the nitrosamine issue initially?
MR. STANOCH: Objection to form.
THE WITNESS: Yes.
MR. STANOCH: Asked and answered.
Go ahead.

Page 294

THE WITNESS: Yes. This is definitely a document I cited. It was very important to my opinions.

And it has a huge distribution list, GNTM, global notice to management, where Teva is communicating to its scores of sites across the globe.

And it starts -- it's an incident category, foreign matter, and it says, "On June 20th, 2018, vendor" ZHP "notified Teva that they came to be aware of a previously unknown impurity that may have genotoxic potential."

BY MS. LOCKARD:

Q. But let me stop you there and ask: So does that clarify for you how Teva learned of the potential --

A. Yes.

Q. -- impurity?

A. Yes.

MR. STANOCH: Objection.

THE WITNESS: And then it --

BY MS. LOCKARD:

Q. Okay. And the next question is: On that date of the initial notification, is there anything there that indicates what the potential impurity

Page 295

was?

A. I don't see that here. I may be missing it, but I don't see that it states the impurity.

Q. You can put that aside for the moment.

Are 483s a final agency determination?

A. No. I would say they are a set of observations from an Office of Regulatory inspector, typically, who is visiting a manufacturing site and writing observations over a several-day period, either in the United States or overseas.

Q. Are warning letters a final agency determination?

A. The way I would say it is the warning letter is an escalation of FDA's concern. I sometimes say it's kind of a shot across the bow of a company, that they better pay closer attention to what FDA is saying and do something.

But even there, the company is allowed to respond, allowed to resolve issues and ultimately allowed to have their manufacturing site cleared of the issues and the inspection closed out by FDA satisfactorily.

Q. So then is a warning letter necessarily a final determination by FDA?

MR. STANOCH: Objection to form.

Page 296

THE WITNESS: No, I would say it is not.

BY MS. LOCKARD:

Q. You were asked some questions about Novartis and testing they allegedly did on some of their products. Do you recall that?

A. I do.

Q. Do you have any information about Novartis' testing of their Diovan or any other products with respect to nitrosamines?

A. No, I don't recall seeing any information, and it was not pertinent to my report.

Q. Do you know why Novartis was testing or what they were testing, if at all?

A. No, I really don't. I have no information about it that I remember.

Q. -- Novartis testing relevant to any of the opinions you have given to date in this case?

MR. STANOCH: Objection.

THE WITNESS: It is not.

BY MS. LOCKARD:

Q. You were asked some questions about the limits of the nitrosamine, either interim limits or permanent limits, by FDA. Are you offering any opinions about whether those limits were appropriate?

Page 297

A. No, I am not.

Q. Have you endeavored to render any opinions about the testing methodology employed to detect limits of nitrosamines?

A. No, it's not part of my opinion, although I mention it in my report.

Q. Do you have any opinions in this case about whether nitrosamines are or are not carcinogenic?

MR. STANOCH: Objection to form.

THE WITNESS: No, I'm not offering any opinion that speaks to pharmacology/toxicology of the nitrosamines.

BY MS. LOCKARD:

Q. Do you intend to offer any opinions about whether nitrosamines in the Teva products were a potential human carcinogen?

MR. STANOCH: Objection to form.

THE WITNESS: No, I don't offer that either.

BY MS. LOCKARD:

Q. Counsel made the point earlier today that even if the USP does not provide for testing of nitrosamines, that a manufacturer can still institute its own testing for nitrosamine.

MR. STANOCH: Objection. There's no question.
THE WITNESS: That's absolutely true. A manufacturer can build additional testing into its private specification working with FDA.
BY MS. LOCKARD:
Q. Well, in order for a company to initiate testing of a genotoxic impurity, what do they need to know?
A. Well, that relates to something FDA said in some of their public announcements. You have to suspect that it's there. You wouldn't test for it if you didn't think it was there, so you first have to have a suspicion that it's there. And then I would say you would have to see some identifiable peak on a chromatogram that raises your concern, and that would lead into an understanding of looking at the impurity and assessing its genotoxic potential.
Q. Did you in this case endeavor to do an independent assessment, at this stage of the case, whether Teva violated any cGMPs?
MR. STANOCH: Objection to form.
THE WITNESS: The only thing I did was look at FDA's record of inspections of Teva's GMPs at its Malta and Jerusalem sites, but I didn't do

any independent evaluation of Teva's GMP adherence.
BY MS. LOCKARD:
Q. Have you endeavored to do any independent assessment of Teva's compliance with any of its policies or procedures?
A. No, not at all. That was not part of my report, and then I didn't cite to any documents to that point.
Q. Now, you were asked about the purpose of your report, and you have heard a lot of objections today about the class-certification opinions that you rendered in your report. Do you have an understanding that you have not been asked by me or my firm to provide any liability opinions at this point in time?
MR. STANOCH: Objection to form.
THE WITNESS: I do understand that.
BY MS. LOCKARD:
Q. Have you intended to give liability opinions today?
A. No.
MR. STANOCH: Objection. Form.
THE WITNESS: I have tried not to give liability opinions.

BY MS. LOCKARD:
Q. Do you understand that at some point we may ask you to review additional materials and render liability opinions?
A. Yes, I understand that may come later on, but it is not happening now.
Q. Are you willing to do that if so asked?
A. Yes.
Q. Are you qualified to do so at certain elements if so asked?
MR. STANOCH: Objection. Form.
THE WITNESS: I believe so.
BY MS. LOCKARD:
Q. You were asked some questions about what do plaintiffs or patients expect; do you remember that?
A. I do remember that.
Q. Do you intend to offer any opinions about plaintiffs' expectations in this case?
MR. STANOCH: Objection to form.
THE WITNESS: No, I mean, I tried to answer those questions as best I could, but they were not part of my report and not part of my opinions.

BY MS. LOCKARD:
Q. Do you intend to offer any opinions about various choices available to plaintiffs who were prescribed hypertension medications; is that what --
MR. STANOCH: Objection to form.
BY MS. LOCKARD:
Q. -- hired to do?
MR. STANOCH: Sorry. Sorry, Counsel. Objection to form.
THE WITNESS: No, I --
(Reporter clarification.)
MR. STANOCH: I apologize. I was just objecting. I'm sorry, Victoria.
THE REPORTER: Okay. So sorry.
BY MS. LOCKARD:
Q. I think I said, is that what you were hired to do?
A. No.
Q. And recognizing you have a medical degree, but do you prescribe, consult, discuss with patients hypertension medications?
A. No, not at all. I am not a practicing clinical doctor.
Q. You were also asked to discuss some issues with respect to recycled solvents in the API that

Page 302

Teva was supplied. Do you recall that?
A. I do.
Q. And are you familiar with recycled solvents being used in pharmaceutical manufacturing?
A. You know, actually I'm not. The first time I read about it was when I started reading materials for this report.
Q. Is it something that you would ordinarily be involved in, in terms of your role at USP or FDA, to investigate recycled solvents?
MR. STANOCH: Objection to form.
THE WITNESS: No. No, really not. To me it seems more like a GMP issue, and I don't speak as a GMP expert.
(Whereupon, a brief discussion off the record.)
BY MS. LOCKARD:
Q. So you don't -- bless you.
You don't intend to offer any opinions in this case criticizing the use of recycled solvents, do you?
MR. STANOCH: Objection.
THE WITNESS: No. As far as I can remember from my report, I don't speak at all to recycled solvents, although FDA speaks about that in

Page 303

their guidance as a source of nitrosamine impurities.
BY MS. LOCKARD:
Q. Which guidance are you referring to?
A. The 2021 nitrosamine impurities guidance.
Q. You aren't aware of any FDA guidance in 2018 or prior that identified recycled solvents as a source of impurities, are you?
A. No. And to me --
MR. STANOCH: Objection.
THE WITNESS: Oh, I'm sorry.
To me it's an example of how FDA and industry learned a great deal from this experience beginning in 2018.
BY MS. LOCKARD:
Q. Ultimately, is it important to your review and opinions whether Mylan was using recycled solvents or not in the API it supplied Teva?
MR. STANOCH: Objection.
THE WITNESS: No, to me it doesn't impact my report one way or the other.
BY MS. LOCKARD:
Q. Does the presence or absence of a quality agreement with Mylan and Teva impact your opinions in your report in any way?

Page 304

A. No. And my understanding is that a quality agreement is not pertinent to the purchase of a drug substance from a manufacturer by a drug-product manufacturer.
Q. You were asked about Teva's submission of their CBE-30 --
A. Yes.
Q. -- for the change in ZHP supply of API; do you recall that?
A. I do recall that.
Q. Based on your experience, do you have any concerns with the use of the CBE-30 to convey those changes to FDA by Teva?
MR. STANOCH: Objection.
THE WITNESS: No, I think Teva, Watson at the time, was following FDA guidance, and if FDA had any concerns, they could certainly have communicated that to Teva right away. And they could have asked Teva to wait and they could have converted it to a postapproval supplement.
BY MS. LOCKARD:
Q. Did they do that?
A. They did not. In fact, in both instances, they approved very rapidly the CBE-30, within days of its submission.

Page 305

Q. You were shown a press release about Ranbaxy and a negotiated guilty plea they entered with respect to their products; do you remember that?
A. I do see it. As a matter of fact, it's still on my screen. I'm looking at it to my right.
Q. And you have read through this document, or to some extent; is that correct?
A. I have an understanding of what it's saying.
Q. And to the extent that the document itself and the negotiated plea deal suggests that there was some retrospective determination that Ranbaxy products were determined to be adulterated, is that analogous in any way to the situation with Teva's products?
MR. STANOCH: Objection to form.
THE WITNESS: This entire matter with Ranbaxy, to me, it is a completely different set of circumstances.
First of all, it involves the Department of Justice. It has a huge civil penalty. It involves fraud and false statements to the agency. It certainly involves GMP violations.
And what happens when you see an

Page 306

announcement like this, you are seeing the result of years of effort on the part of FDA and the Department of Justice to have Ranbaxy agree to a set of statements, including the statement about adulteration in the prior years.

So I would say it has no relationship at all to my current report or my opinions.

BY MS. LOCKARD:

Q. So in the Ranbaxy situation, was the language that was referenced about adulteration, to your knowledge, was that the product of negotiation between Ranbaxy --

MR. STANOCH: Objection to the --

(Reporter clarification.)

BY MS. LOCKARD:

Q. Government?

THE REPORTER: Thank you.

MR. STANOCH: Objection. Objection.

THE WITNESS: Well, to the extent I know what happened here, and I know it was a very detailed effort on the part of the agency, yes, it was a negotiated settlement where Ranbaxy and FDA and the Department of Justice are agreeing to the statement that appears on my screen.

Page 307

BY MS. LOCKARD:

Q. To your knowledge, has Teva been involved in any DOJ investigation, criminal proceeding, FDA fines, like that described in the Ranbaxy press release with respect to its --

A. No, I have not --

(Whereupon, a brief discussion off the record.)

BY MS. LOCKARD:

Q. Okay. My question to you, Dr. Williams, was: To your knowledge, has Teva been involved in any DOJ investigation, criminal proceeding, FDA fines or fraud with respect to its valsartan like that that was described in this Ranbaxy press release that you were provided today?

MR. STANOCH: Objection.

THE WITNESS: Not at all.

BY MS. LOCKARD:

Q. Does this Ranbaxy press release and the findings in any way undercut your opinions that you have rendered in this case about Teva's valsartan not being adulterated?

MR. STANOCH: Objection.

THE WITNESS: No, not at all.

Page 308

BY MS. LOCKARD:

Q. The confidentiality of DMFs was discussed earlier today. Do you remember that?

A. I do.

Q. Is there any part of the DMF that FDA actually considers to be open?

A. If we look at some of the documents I cited, you will see that FDA considers the DMF entirely confidential. In Europe sometimes they talk about an open part or a closed part, but FDA thinks of it as all closed, all confidential.

Q. You had said that theoretically you suppose companies could decide on their own to share, but are you familiar with that happening in this case?

MR. STANOCH: Objection.

THE WITNESS: I'm not, and it seems unusual. It seems to undercut the purpose of the DMF, which is to keep some parts of it confidential.

What the buyer, in this case the ANDA holder, would see is the certificate of analysis, which is the specification you use to test the drug substance, and that's all they would see.

BY MS. LOCKARD:

Q. And in this situation, would you expect

Page 309

Teva and its API suppliers to share the DMF or supply Teva with anything other than the certificate of analyses?

MR. STANOCH: Objection to form.

THE WITNESS: I didn't see any documents otherwise, so my belief is that the two drug-substance manufacturers were keeping their DMF confidential, as is typical of the way DMFs are handled.

BY MS. LOCKARD:

Q. Right. So is it surprising to you if you learn that the companies in this case didn't -- did not share the DMF portion?

A. That would not be surprising.

MR. STANOCH: Objection.

THE WITNESS: That would not be surprising. That would be typical.

BY MS. LOCKARD:

Q. Now, you were asked a line of questions referencing back to your report, and it was under "The FDA Drug Approval Process" section in your report. You were asked about a line that said, "A recall is a voluntary action taken by a company to remove a defective drug product from the market."

Do you recall that?

Page 310

MR. STANOCH: Objection.
THE WITNESS: I do recall that.
BY MS. LOCKARD:
Q. And had you taken that as a quote from an FDA general statement about drug recalls?
MR. STANOCH: Objection.
THE WITNESS: I think if we look at the FDA website and see what it says about recalls, that is what it says. That's the terminology they use.
BY MS. LOCKARD:
Q. Can a recall occur for reasons other than a defective product?
MR. STANOCH: Objection.
THE WITNESS: Well, I would say this is an interesting example, because at the time Teva and FDA agreed to recall their valsartan products, there was no understanding the products were defective. They were not defective. FDA had not set limits on nitrosamine impurities. But still FDA and Teva agreed that they should come off the market because of the presence of the nitrosamine impurities.
Later on, when FDA set limits, you could say, well, they might have been considered adulterated, but in the summer of 2018, with regard to the ZHP drug substance, I do not see them as

Page 311

being defective products.
BY MS. LOCKARD:
Q. So just to be clear, do you hold any opinion that the valsartan products that were sold to customers by Teva were sold in a defective state?
MR. STANOCH: Objection to form.
THE WITNESS: I wouldn't use those words, and that is not part of my opinion.
BY MS. LOCKARD:
Q. Does the presence -- does the sheer presence of any nitrosamine render a product defective?
MR. STANOCH: Objection to form.
THE WITNESS: No. I would say, particularly if we look at the nitrosamine guidance, FDA will allow nitrosamine impurities in ingredients and products as long as they stay within acceptable intake limits.
BY MS. LOCKARD:
Q. So is it your opinion that if a drug product is sold -- well, strike that.
You were asked about Exhibit 14. See if we can get a copy of that for you. It was an interview in the Pharmacy Times.
A. I don't think I have that.

Page 312

Q. Let's see, actually.
A. Oh.
Q. Pull that out of my --
A. Oh.
Q. It's there.
A. Yes. I see it, thank you.
Q. Are you familiar with the Pharmacy Times?
A. Yes, somewhat.
Q. Have you ever seen this article before today?
A. No, I have not.
Q. Do you see what the date on this article was?
A. June 29th, 2021.
Q. Are you familiar with Edwin Gump?
A. I actually am not.
Q. Are you familiar with the Small Molecules Department at U.S. Pharmacopeia, USP?
A. Yes.
MR. STANOCH: Objection. Form.
THE WITNESS: I would say I helped create that department when I first came to USP in 2000.
BY MS. LOCKARD:
Q. There is also a reference on the second page to the USP Nitrosamines Joint Subcommittee.

Page 313

Was that a subcommittee in effect at FDA when you were there?
A. No, it was not.
Q. When was that formed, if you know?
A. I actually don't know, and I'm not sure I see where you are reading. Could you help me, Ms. Lockard?
Q. If you are looking at the bottom of what is page 2. Are you with me there?
A. Actually, I am still not. There is something where it speaks to a subcommittee of an expert committee?
Q. Yeah, it is the very end of page 2, where it says "Alana Hippensteele," she says, "That's fascinating."
A. Oh.
Q. "What is the USP Nitrosamines Joint Subcommittee" --
A. Yes, I see.
Q. -- "and why was it established?" Do you see that?
A. Yes, I can, you know, understand, I think, what that subcommittee was doing and how it was formed.
Q. Okay. Can you explain briefly your

Page 314

understanding of what it was doing and how it was formed?
A. Well, USP has the Council of Experts, which has many expert committees. But the expert committees have the possibility of forming subcommittees, drawing on expertise from different committees. So I see a subcommittee being formed jointly from several expert committees to consider particularly the topic of nitrosamines in small-molecule medicines.
Q. To your knowledge, did the USP Nitrosamines Joint Subcommittee exist before 2018?
A. I don't know that. As far as I know, it didn't exist.
Q. All right. So if you turn to page 4, I believe you were asked to read some of the text on this page, and you were asked if you agreed with it. Do you remember that?
A. Page 4. Is this the one down at the bottom where he's talking about the grilled burger?
Q. Let me see. I know the pages aren't numbered, which makes it difficult, but I'm just counting three, four.
A. Oh, okay. All right. Thank you.
Q. Okay. So the very last paragraph on

Page 315

page 4, that begins, "So, and again"; do you see that?
A. Yes, I do see that.
Q. Oh, good. Can you read that paragraph as well?
A. "So, and again, I think I mentioned, we're talking about really ultratrace levels, parts per million, part per billion. So, these are not easy analyses to perform. They require highly complex analytical equipment, and with any test, you need to kind of have what's the control to that test."
Q. So do you agree with that statement?
A. I certainly do.
Q. And if you look at the following page, first paragraph.
A. Yes, and I can read it, but I think what USP is doing is talking about its reference materials, and they are talking about reference materials for nitrosamine impurities.
Q. And in Paragraph 2 it says, "So, having the reference standards is a really important tool for manufacturers."
A. Yeah.
Q. Did I read that correctly?
A. Yes, that's quite true.

Page 316

Q. And if you skip down, midway on the page Edwin Gump is speaking.
A. He is.
Q. He says, "It's a good question. So, one of the things that I think the pharmaceutical industry has generally for the most part done very well is look at impurities." Do you agree with that?
A. I do.
Q. He goes on to say, "I think nitrosamines, for the reasons I just described, are kind of a unique case where they can sort of crop up." Do you agree with that?
A. I do agree with that.
Q. He goes on, "They aren't necessarily readily identified as part of the components during the manufacturing process, and so they sort of slip through." Is that your understanding as well?
A. I think I could agree with that.
Q. "Whereas, other types of impurities, I think, manufacturers have a" "better handle on how to control those."
A. Yes, I think he is speaking to what I was trying to comment on as well, that there are sort of general ways of dealing with impurities, but the

Page 317

nitrosamine impurities are -- as FDA said, are very unusual, unexpected. You have to think that they may be there, and then even when you think that, they are at very low levels and require very special techniques to measure.
Q. So towards the bottom of the page, finally, Mr. Gump is saying, "It really is, I think, a lot better than people think. You tend to hear about the few problems that occur, but you don't hear about the millions or billions of pills that get distributed every year and help people deal with their health conditions." Do you agree with that sentiment?
A. I can certainly attest to that.
Q. So, Dr. Williams, you know, just to be clear for the record, you weren't really asked much about your report and your opinions in it. But have you heard anything today that causes you to change your opinions as stated in your expert report?
MR. STANOCH: Objection to form.
THE WITNESS: No, nothing at all.
BY MS. LOCKARD:
Q. Have you been shown any documents today or testimony that changes your opinion in any way?
A. No.

Page 318

Q. So in terms of, really, if we can get to the heart of your opinions, what are your core opinions in this case?

MR. STANOCH: Objection.

THE WITNESS: You know, the way I would summarize those, I think they appear in the last page or two of my report, and I'll try to say it this way.

Teva's products, all four valsartan-containing drug products were always pharmaceutically equivalent and bioequivalent to the Diovan reference listed drugs made by Novartis. While they were in the market, they were always AB-rated by FDA. They were not misbranded because FDA required them to have substantively the same label as Diovan.

And they were not adulterated in my view until -- and you could even debate it after that point, but they certainly were not adulterated or defective until FDA issued warning letters to ZHP and Mylan or when FDA set limits in December of 2019.

So what you have -- and I said it in the report, it's a very unusual situation, where we all know nitrosamine impurities can be genotoxic. We

Page 319

know they are very low level. They are hard to measure. They can creep into a product, as Dr. Gump said.

And FDA and Teva in the summer of '22 (verbatim) were faced with this issue. Well, we have got them there. What are we going to do? And FDA and Teva working together decided to recall, first, all the ZHP products from the market before there was any possibility of a decision about adulteration, and then subsequently, after the Swissmedic report, all the Mylan product from the market, again, before there was any possibility of a decision about adulteration.

As I said in the report, this is not a failure. This is a success story where a responsible company is making a huge effort to protect consumers, to protect patients, and FDA is working very hard to find out what is going on.

It spills over into other products. It keeps spilling over into other products. And now FDA is asking that essentially all chemical medicines in the market or being developed for the market be assessed for nitrosamine impurities.

I'm gratified with the effort. This is how drug regulation advances. And I just don't see

Page 320

that Teva did anything wrong and everything right.

MS. LOCKARD: I don't have any more questions for you at this time. I imagine there may be more questions. Thank you, Dr. Williams. And I may follow up.

EXAMINATION

BY MR. STANOCH:

Q. Dr. Williams, prior to your question-and-answer session with Ms. Lockard, you spoke with her during the lengthy 35-minute break, didn't you?

MS. LOCKARD: Object to form. Argumentative.

THE WITNESS: I would say I sat there and listened to her talk out how she was going to question me, but I really didn't engage in that discussion in any substantive way.

MR. STANOCH: Stand by.

Nothing further, Doctor.

MS. LOCKARD: Any other questions from others?

MR. STANOCH: And, Counsel, I'll just ask on the record that the binder of potential exhibits be destroyed or returned to me without looking at it, please.

Page 321

MS. LOCKARD: All right. I did take the exhibits you used out of the binder.

MR. STANOCH: That's fair. I understand. Thank you.

MS. LOCKARD: I'll put them back. But I didn't remove the ones that you haven't used and I haven't looked at all of those, so --

MR. STANOCH: I appreciate that. Thank you, Counsel.

THE VIDEOGRAPHER: Anything further on the record?

Okay. Well, this concludes today's deposition of Dr. Roger Williams. We are going off the record at 4:24.

(Whereupon, the deposition was concluded at 4:24 p.m.)

INSTRUCTIONS TO WITNESS

Please read your deposition over carefully and make any necessary corrections. You should state the reason in the appropriate space on the errata sheet for any corrections that are made.

After doing so, please sign the errata sheet and date it.

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ACKNOWLEDGMENT OF DEPONENT

I,_____, do hereby certify that I have read the foregoing pages, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

_____ _____
ROGER WILLIAMS, M.D. DATE

STATE OF CALIFORNIA)
COUNTY OF YOLO)

I, ELAINA BULDA-JONES, a Certified Shorthand Reporter of the State of California, duly authorized to administer oaths pursuant to Section 2025 of the California Code of Civil Procedure, do hereby certify that

ROGER WILLIAMS, M.D.,

the witness in the foregoing deposition, was by me duly sworn to testify the truth, the whole truth and nothing but the truth in the within-entitled cause; that said testimony of said witness was reported by me, a disinterested person, and was thereafter transcribed under my direction into typewriting and is a true and correct transcription of said proceedings.

I further certify that I am not of counsel or attorney for either or any of the parties in the foregoing deposition and caption named, nor in any way interested in the outcome of the cause named in said deposition dated the 22nd day of February, 2022.

ELAINA BULDA-JONES, CSR 11720

WORD INDEX